UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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STAKEHOLDER MEETING

HHS IMPORTATION TASK FORCE

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INDUSTRY: DEVELOPMENT & DISTRIBUTION

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Monday, April 5, 2004

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The above-entitled matter was held at 2:00 p.m. in Parklawn Conference Room E, 5600 Fishers Lane, Rockville, Maryland, VADM Richard Carmona, Task Force Chair, presiding.

TASK FORCE MEMBERS PRESENT:

VADM RICHARD CARMONA, Chairman

MR. JAYSON P. AHERN

MR. ALEX M. AZAR, II

MS. JOSEFINA CARBONELL

DR. LESTER M. CRAWFORD

DR. BETTY JAMES DUKE

DR. MARK B. McCLELLAN

DR. MIKE O'GRADY

TASK FORCE MEMBERS PRESENT (Continued):

DR. WILLIAM RAUB

MR. TOM REILLY

MR. AMIT K. SACHDEV

DR. ELIZABETH A. WILLIS

PRESENTERS:

Panel 1:

Healthcare Distribution Management Association

Mark Parrish, President of Cardinal Health, Inc.

McKesson Corporation

Paul Julian, Chief Operating Officer

Pharmaceutical Distributors Association

John M. Stinson, Partner, Law Firm of Forsay & Stinson, PLLC

National Association of Chain Drug Stores

Larry Kocot, Senior Vice-President of Policy Programs and Legal

Massachusetts Institute of Technology Auto-ID Lab

Dr. Robin Koh

Department of the Treasury

Thomas Ferguson, Director, Bureau of Engraving and Printing

United Parcel Service

Robert Bergman, Vice President Public Affairs

PRESENTERS (Continued):

Panel 2:

Barr Laboratories

Bruce Downey, Chairman and CEO

Eli Lilly & Company

Dillard W. "Buz" Howell, II, Director of Global Product Protection

Pfizer

John Theriault, Vice President of Global Security

Johnson & Johnson

John Dempsey, Executive Director of Trade Relations and Brand Security for Ortho Biotech

Serono Laboratories, Inc.

Pamela Williamson, Vice President of Regulatory Affairs

Generic Pharmaceutical Association

Gordon Johnston, Vice President of Regulatory Affairs for GPhA

C O N T E N T S

PRESENTATION BY: PAGE

Panel 1:

Panel 2:

P R O C E E D I N G S

(2:06 p.m.)

CHAIRMAN CARMONA: Thank you all for being here.

I'm Dr. Richard Carmona. I'm the U.S. Surgeon General.

I'd like to welcome you to the second listening session of the Task Force on Drug Importation. Today we will hear from representatives to discuss pharmaceutical development and distribution.

As you know, the safety and efficacy questions related to importing prescription drugs into our country are very important to public health. Secretary Thompson formed this Task Force to explore whether and how drug importation might be conducted safely and its potential impact on the health of American patients, medical costs, and the development of new medicines.

Together this Task Force and the stakeholders we are consulting will research and explore whether prescription drug importation can be done safely and effectively, and if so, what resources are needed.

Our mission outlined in the Medicare Prescription Drug Improvement and Modernization Act

of 2003 is to determine whether there is a safe structure for prescription drug importation.

I was again reassured this week that we have the full support of the White House and the Secretary to take any steps necessary to fulfill that mission.

Our first listening session on March 19th was with consumer and advocacy groups. Those presenters offered useful background and suggestions, and I thank them not only for their thoughtful presentations, but also for their responses to our follow-up questions.

As I did at our first session, I want to promise all of the presenters today and in the future listening sessions the opportunity to be heard. I expect this process to be completely transparent with frank, open, and honest discussion about the health implications of drug importation. I expect that the diverse ideas will be presented and I ask everyone to be respectful of that diversity.

This Task Force is, first and foremost, about the facts and the science, and we will go as far as the facts and the science lead us. I thank everyone in advance for keeping this in mind.

These listening sessions will be

conducted in an organized manner in an effort to produce the best information possible. Each presenter will have up to five minutes for opening remarks. After all presenters on the panel have concluded their statements, the Task Force members may follow up with some questions.

I ask each presenter to please be mindful of the five minute limit for presentations so that we can insure that everyone has equal opportunity to be heard.

In addition, the Task Force will welcome all written and supporting materials that parties would like to submit. Those materials, along with the transcript of each listening session, will be available to the public.

The Department of Health and Human Services has developed a Web site for the Task Force that can be reached through www.hhs.gov. We have received good response at that site from individuals who want to make presentations at the Task Force meeting on April 14th, which is the public meeting, and HHS extended the deadline for registration through April 6th.

With that, let's get going with today's business, and I'd like to welcome the first panel of presenters, and why don't we start from my left

then with Mr. Mark Parrish.

MR. PARRISH: Good afternoon, Mr. Chairman and members of the Task Force. I thank you for inviting me to participate in today's important round table.

My name is Mark Parrish, and I'm the Executive Vice President of Cardinal Health, a health care products services and distribution company. However, I am here today in my role as a member of the Board of Directors and Executive Committee of the Healthcare Distributors Management Association.

HDMA is a national trade association representing full service distribution companies responsible for insuring that billions of units of medication safely make their way to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States.

Since product integrity and patient safety are HDMA's most important priorities, I'm honored to have this opportunity to highlight our perspectives on this extremely important study. When considering importation, I think we can all agree that the most important consideration is to insure patient safety.

With that shared goal in mind, we believe that there are three key areas that any approach to importation must address.

First is product authentication. When our citizens order their medication, it must be assured that they receive the drug in the exact specification their physician requires. This sounds simple; yet products are produced differently for different markets based on differing standards, in addition to legal differences in same brand name pharmaceuticals. We know that counterfeiting is a much more pervasive criminal activity outside the United States, and we must protect against the effects of this insidious practice.

The second area is product integrity. When a patient is in need of medication, there should never be a question about the strength or safety it possesses. We cannot allow a system to be developed that does not properly address the multitude of factors that cause degradation of pharmaceuticals.

The third issue is the availability of supply. There are significant challenges to insure proper authentication and integrity of imported pharmaceuticals. Base on our experience, we would

like to highlight several issues to be considered by this Task Force.

First, authentication. It must be assured that any imported drug is the U.S. formulation of the product made in a U.S. approved manufacturing facility. To avoid any chance that an imported product is counterfeit, substandard or otherwise unsuitable for U.S. patients, it is imperative to determine these two critical factors.

Product testing has been identified as a means to verify authenticity, but this method will fall short if tests don't consider both the active and inactive ingredients which make up the total formulation of the drug. To insure that imported drug is the U.S. approved formulation made in a U.S. approved plant requires either certification from the manufacturer or analytical testing for all of the inactive ingredients.

Similarly, the active ingredient would need to be certified, which would require a comprehensive profiling of the imported product or certification from the manufacturer.

In addition, since we know that counterfeiting is a random event, to totally protect against counterfeit drugs from entering the U.S. market, every lot from every shipment would

have to be tested, not just random samples.

Considering the sophistication of the testing and the frequency with which it would have to be done, this would prove to be costly. While the challenge of authenticating imported supply is significant, the second area to address, product integrity, is perhaps even more complex and multifaceted. The supply chain both inside the U.S. and outside the U.S. would need to be linear. This means that product would have to flow from manufacturer to exporter to importer to pharmacy in order to verify the authenticity.

Moreover, there must be rigorous regulatory standards, registration requirements, and inspection programs specifically designed to insure all those engaged in exporting and importing pharmaceuticals, including Internet pharmacy, are suitably qualified and possess the skills, infrastructure, and the interest to protect the integrity of the supply chain.

Climate control, safe handling practices, and strict adherence to the manufacturer's specifications are just a few of the important ways that wholesalers protect the integrity of the U.S. drug supply.

In addition to product efficacy, the

third issue that must be addressed is product supply and demand. There will likely not be enough products to meet the domestic demand under importation. For example, U.S. pharmacists fill about ten times the number of prescriptions as are filled by their counterparts in Canada.

An environment of strong demand with low supply from Canada or other approved exporting countries would open the door for transshipment of prescription drugs from other areas of the world and likely attract diverted, counterfeit, subpotent, or adulterated products.

In summary, with patient safety as our paramount goal, if a decision to move forward with importation is made, wholesalers with systems and infrastructures in place to protect product integrity and detect and deter counterfeit drugs would be best equipped to maintain the safety and security of the national drug supply.

As I've said during my remarks, there are significant challenges that must be addressed to insure the broad safety of imported products, while maintaining the desired cost benefits for consumers. Should the FDA pursue importation, the three areas that I have outlined today, product authentication, product integrity, and

availability, must be thoroughly addressed.

There are many other factors that will also need evaluation. I have focused my comments on the most significant today.

CHAIRMAN CARMONA: Thank you very much, sir.

Next we have Mr. Paul Julian from McKesson.

MR. JULIAN: Mr. Chairman and members of the Task Force on Importation, my name is Paul Julian, and I am President of McKesson Supply Solutions.

McKesson commends the agency for undertaking a study of drug importation, and we appreciate the opportunity to share our perspective.

McKesson is the largest pharmaceutical supply, management, and health information technology company in the world. We are also the largest pharmaceutical distributor in North America through our ownership of McKesson Canada, the leading wholesale distributor in Canada, and our equity holding in Nadro, a leading distributor in Mexico.

McKesson has strict policies and procedures in place that both insure the safety of

the products we distribute and exceed the safety requirements of the countries in which we operate. We source 99.5 percent of our products in the U.S. and 100 percent of our products in Canada directly from the manufacturers.

McKesson has serious concerns that a broad based importation system may not assure both product safety and cost savings to the American consumer. However, it is possible that these issues could be addressed through a narrow, closed distribution system.

Under such a system, pharmaceutical distributors with appropriate technology experience and distribution networks on both sides of the border could safely transfer products between their distribution centers in Canada and their distribution centers in the United States.

To assure safety, these distributors must source 100 percent of their products directly from the manufacturers. Clearly, such a system would depend on the availability of product in Canada, the cooperation of key members of the supply chain, and the development of an allocation system to insure equitable distribution to the American public.

Of course, from our perspective, any

system that is developed has to be compatible with our commercial agreements.

It is important to recognize the U.S. demand for lower priced pharmaceuticals will always exceed the available supply from Canada or from any other exporting country. This imbalance in demand will require an allocation system to insure equitable distribution of the available imported pharmaceutical products.

McKesson recognizes that any allocation policy will be highly controversial and will require government intervention.

If an importation system is devised, we believe there are significant challenges that may make it difficult to safely provide an adequate supply of lower priced product.

To insure a secure and cost effective supply chain, the Task Force must address the following issues. The Canadian government has stated that it cannot guarantee the safety of drugs shipped to the United States. At the same time, the U.S. lacks the resources to adequately monitor products shipped directly to patients over the border.

Actual or alleged transshipment of product through Canada could result in the

development of a gray market that is difficult to monitor. Adequate regulations, criminal penalties and supporting resources are needed to prevent the shipment through Canada of pharmaceutical products that are improperly stored or handled, subpotent, expired, adulterated, or counterfeit.

Appropriate testing of imported products may be required to insure safety and potency. Should patient or product safety concerns necessitate relabeling or repackaging of imported products, additional costs will ensue.

The use of electronic technology to track products in foreign countries would help to insure that products are sourced in FDA approved facilities and shipped through legitimate wholesale channels prior to the sale in the United States.

The effective implementation of such a system for importation, however, poses significant challenges. Pharmaceutical manufacturers must agree to tag products globally at the time of manufacture and our intermediaries must adopt the electronic reading technology.

Product recalls are currently initiated by the manufacturer and facilitated by wholesalers and pharmacies. Most recalls are national in scope, not global.

It will be necessary to establish a process for recalls in the absence of a single governing body that has jurisdictions on both sides of the border.

There are also additional costs associated with imported products. Canadian price controls exist for Canadian citizens, not for the export market. In a legalized importation environment between the U.S. and Canada, we expect the prices at which Canadian entities sell to the U.S. to rise as demand exceeds available supply.

Generic pharmaceuticals are generally less expensive in the United States than in Canada and account for approximately 45 percent of the unit volume of drugs consumed in the United States. Under legalized importation, consumers may ultimately pay more to import a branded product than they would for a domestic generic product that is readily available.

Reimbursement for pharmaceutical products by third party payers will need to be thoughtfully addressed in any importation system. It remains unclear as to what extent health insurance and government payers, including CMS, would reimburse pharmacies and patients for foreign secured product.

The importation of pharmaceutical products is also likely to entail the assumption of additional liability. Without regulations governing liability for imported product, it is unclear who would bear liability for any adverse drug events associated with products sold outside their country of intended use.

In conclusion, given our unique capabilities in Canada and the U.S., we stand ready to share our expertise to help the Task Force better understand safety and cost issues associated with drug importation. McKesson is committed to removing unnecessary costs from the health care system as we insure the timely delivery of safe, cost effective products.

We remain concerned about the safety, cost, and allocation issues which we believe could present significant barriers to the successful implementation of any importation system.

Again, thank you for providing us with the opportunity to testify today, and I would be happy to respond to any questions.

CHAIRMAN CARMONA: Thank you, sir.

Our next speaker, Mr. John Stinson.

MR. STINSON: Thank you, sir.

Mr. Chairman, members of the Task

Force, my name is John Stinson, and I'm here today representing the Pharmaceutical Distributors Association.

PDA is an association of small prescription drug wholesalers. The three major wholesalers, national wholesalers represented here, distribute 90 percent of the pharmaceuticals in the United States. PDA represents the interests of smaller wholesalers who distribute regionally to pharmacies, to specialty markets, and to other distributors.

Small wholesalers are an essential part of the nation's pharmaceutical supply system and are critical to competitive and efficient drug distribution in the United States.

While PDA has never taken an aggressive posture on the issues of drug importation, our members believe that small wholesalers should be involved in the developments and any evolution of such changes in the law which will create a market.

We are concerned that the current safety nets are not compromised, and utmost, the needs of the patient safety is considered.

Because most manufacturers make the same color, shape and dosage drug for the world market, those who attempt to import drugs in the

United States must exercise substantial due diligence to assure that the drugs they're importing are the drugs manufactured and labeled pursuant to new drug applications.

In this regard, importers must assure that the drug being provided is the NDA approved drug with appropriate labeling, and not labeling intended for non-U.S. customers.

In addition, importers must assure that the drug packaging size, lot, and lot numbers coincide with sizes and lot numbers packaged and labeled by manufacturers for the U.S. market.

Because importers do not usually buy directly from manufacturers, it is often difficult to assure that the drug they are buying has not been repackaged from unapproved U.S. labeling into U.S. labeling.

In addition, because the transaction history of the drug may not be ascertainable, it is difficult to assure that the drug is the approved new drug and not a counterfeit.

When prescriptions are imported into the United States in wholesale quantities, it is our understanding that FDA, working with U.S. Customs checks to determine that the products are not altered or misbranded.

In this regard, FDA may ascertain whether there is an NDA for the drug. What we believe FDA does not do is ascertain whether there is assurance that the drugs being imported are the approved new drugs, as discussed above.

Therefore, such drugs have been repackaged from foreign labeling. They may not be identified as unapproved new drugs as the drugs are imported. The overall issues are complicated, at best.

Against this background, the wholesale importation of prescription drugs in the United States is presently a perilous exercise. Any changes to the current drug safety should be taken with maximum care. PDA believes that any policy decision to change the law to facilitate the importation or reimportation of prescription drugs must involve licensed prescription drug wholesalers and must require a controlled and regulated environment where the integrity of imported drugs can be confirmed and maintained.

PDA appreciates the opportunity to be here today, and we look forward to discussing these issues with you.

CHAIRMAN CARMONA: Thank you, sir.

Our next speaker, Dr. Robin Koh, MIT.

DR. KOH: Thank you.

Mr. Chairman and members of the Task Force on Importation, thank you for the opportunity to brief you on a new automatic identification and data capture technology called Auto ID.

My name is Robin Koh, and I'm here in the capacity of Director of Applications Research at Auto ID Labs at MIT.

The Auto ID Center was opened at MIT in October, 1999, to develop the infrastructure and standards for a new generation of automatic identification and data capture technology to replace the bar code. The center has designed, built, tested, and deployed a global infrastructure layered on top of the Internet which makes it possible to identify, track, and trace objects around the world.

The Auto ID system is an intelligent, ubiquitous infrastructure that automatically and seamlessly links physical objects to the global Internet. This system networks physical objects without human intervention or manipulation by automated machines.

This is accomplished by integrating an electronic radio frequency identification tag, otherwise known as RFID, into the object. A

network of tag readers and local data collection and control systems, called Savants (phonetic), are used to automatically communicate with the physical objects and automate control applications.

The ubiquitous nature of the Auto ID system requires that it be inexpensive to implement relative to the benefits achieved by applications that utilize the systems, such as supply chain management. The extreme low cost required to actually implement the system has been an overriding constraint in the design of the auto ID system. The cost of tags for millions of objects is the dominant cost of the system.

Consequently, the tag costs and, therefore, its functionality was minimized. The resulting cheap tag stores only a unique identifier, the electronic product code known as EPC, for a particular object.

The unique object identifier is global in scope and acts as a pointer to information stored about the object somewhere over the information network. A redirection service, the object name service, is used in conjunction with the electronic product code to identify the location of information and related services for a particular object. The object name service allows

for the location or locally available information, as well as globally available information.

The information must be stored in a standard language to enable true automation, which is required in supply chains. The Auto ID system utilizes an XML based language called the physical mark-up language to standardize the description of physical objects and their properties.

Therefore, there are three major components of the auto ID system: the radio frequency identification tags, the software backbone of the system and the standards of the technology.

Securing the pharmaceutical supply chain. Auto ID technology enables two fundamental supply chain-wide approaches to deal with counterfeit drugs and drugs not fit for consumption. Both of these approaches complement the current anti-counterfeit overt and covert technologies employed by the pharmaceutical industry.

First, Auto ID technology allows the possibility of instant authentication for any drug at any location. This authentication process is possible through an information technology infrastructure that spans the complete supply

chain. During the authentication process we would be able to find out the most current status of the product, for example, whether it has been expired, been recalled, or discarded.

Second, Auto ID technology allows the ability to do robust track and trace. Tracking is defined as the control of a product as it moves through the supply chain while tracing is the building of a history behind a particular product. Tracing is also commonly known as product pedigree.

In tracking product is accounted for and passed on from one supply chain partner to the next on a real time basis. This insures that goods are accounted for throughout the supply chain and end up where they are supposed to go. Deviations can be accounted for quickly and acted upon.

In tracing, the Auto ID system can be used to systematically access databases of all companies or entities that have handled the product. This helps us build an electronic pedigree for that particular product.

The authentication track and trace approach, as mentioned above, depend heavily on the capability to uniquely identify individual drugs within the supply chain at the primary package

level.

The electronic product code is applied to each primary package unit, and this is the basis for mass serialization of pharmaceutical product. Using bar code systems to read and account for billions of unique identifiers is laborious, and RFID holds out the promise holds out the promise of a more efficient technology to execute this mass serialization in the supply chain.

In conclusion, the Auto ID system holds promise of making pharmaceutical products in the supply chain much more secure than they are today. The EPC community and Auto ID labs are committed to doing all that is possible to remove the barriers to the widespread global adoption of this technology.

Thank you, and we appreciate your interest in auto ID.

CHAIRMAN CARMONA: Thank you, Doctor.

Let's drop back now to Mr. Larry Kocot. Thank you very much, sir.

MR. KOCOT: Thank you.

And I apologize for being late.

Mr. Chairman and members of the Task Force, my name is Larry Kocot, and I'm Senior Vice President and General Counsel with the National

Association of Chain Drug Stores (NACDS).

NACDS appreciates the opportunity to be with you today to participate in this forum on importation. NACDS is a national trade association representing more than 207 chain pharmacy companies operating nearly 32,000 community retail pharmacies. Our members dispense more than 70 percent of all out-patient retail prescriptions in the United States.

The Medicare Prescription Drug Improvement and Modernization Act gives the Secretary the authority to implement a system for the importation of Canadian prescription drugs, but only if he's first able to certify to the Congress that it would be safe and cost effective. The act contemplates two different methods of importation prescription drugs that should be distinguished and evaluated separately in terms of their safety and their cost effectiveness.

First, the act directs the Secretary to consider certain factors in enforcing prohibitions on individuals importing prescription drugs and allows the Secretary to grant waivers to individuals to allow importation for personal use.

While NACDS supports access to low cost prescription drugs, NACDS is opposed to proposals

that would encourage or facilitate the importation of prescription drugs by individuals.

Simply put, there's no realistic way right now for consumers to know whether the imported prescription medications are adulterated, counterfeit, or even approved for use in the United States. As recent federal reports have shown and the investigations have shown, millions of packages containing pharmaceutical products, many mislabeled, contaminated, adulterated, counterfeit or harmful controlled substances are being shipped into the United States each year.

Patients assume an incredible risk when they shop internationally for drugs. As we have found, many Canadian or so-called Canadian pharmacies are not what they advertise, and the drugs are from questionable sources.

If the drug is subpotent, adulterated, or otherwise ineffective, any savings that someone thinks that they may have received is lost, and the money is wasted.

Additionally, individual importation of prescription drugs often eliminates a patient's interaction with the pharmacist. This interaction is important to insure that the patient understands how to take the medication appropriately, and with

no knowledge of a patient's foreign purchases, a patient's pharmacist cannot protect the patient from a harmful drug interaction or reaction.

The cost of hospitalization for a drug event far exceeds any savings that a patient may have realized on the purchase of a prescription drug. Importantly, patients in pursuit of cheaper prescription drugs from Canada may miss altogether the fact that generic drugs are still much less expensive on this side of the border.

Finally, there is broad economic cost that must be considered when we send patients to foreign countries for prescriptions. Importation schemes promote unfair competition against American pharmacies. For example, foreign pharmacies don't pay U.S. taxes. Foreign pharmacies are not subject to federal or state consumer protection laws. Foreign pharmacies don't have to comply with stringent federal and state licensure requirements and U.S. safety standards. Foreign pharmacies don't face the frequent lawsuits that are an ever growing threat in the United States to U.S. businesses. Indeed, they often require customers to waive all liability, which we in American companies cannot do and certainly wouldn't do.

Foreign pharmacies do not comply with

the thousands of laws and regulations that apply to U.S. pharmacies, such as the stringent HIPAA privacy rules that protect patients against the improper use and disclosure of their personal health information. Indeed, HHS recently told NACDS that many Canadian storefronts facilitating importation are not even subject to HIPAA.

As a result, no United States citizen should have the false expectation that their private medical records will not be sold or traded on the international market to unscrupulous marketers.

The act also contemplates a system of importation by pharmacists to wholesalers. We believe there are significant challenges to implementing a program of importation of prescription drugs by pharmacists and wholesalers.

For example, which parties will bear the liability if imported drugs result in harm to individuals? Pharmacists may not be able to accept the liability that comes with a program of importation.

We are concerned that the testing, tracking, and paper work requirements of this law could outweigh any cost savings. Some of this

testing and record keeping information may be difficult or impossible for an importer to obtain or validate.

Moreover, establishing the infrastructure necessary to effectively and efficiently operate an importation program would impose significant start-up costs on the entire pharmaceutical distribution system.

The bottom line is that once the cost of importation is factored into the overall pricing equation, we can't be certain that the price of imported medications would be significantly less expensive than prices for prescription medications in the United States. After all, the supply of available drugs from Canada is relatively small. IMS Health reports dollar sales for prescription drugs in the United States totaled approximately $214 billion in 2003. According to IMS, Canadian drug sales totaled about nine billion in 2003.

Therefore, assuming we'd leave the Canadians with some drug supply for their own population, the theoretically available cheaper drug supply from Canada approximates the number substantially less than nine billion.

To put this in perspective, CVS alone could purchase all of the Canadian drug supply and

still not satisfy its prescription drug inventory needs for one year.

Basic laws of supply and demand dictate one of two things will happen with the Canadian drug supply if the United States implements a system of drug importation by American wholesalers and pharmacists. Either prices will rise dramatically in Canada or Canadian supplies will turn to alternative foreign suppliers that would likely be unacceptable to the United States and its purchasers.

In either case, implementation of a successful United States importation program would likely be more costly than any theoretical savings we could derive from buying up the entire Canadian drug supply.

It's unrealistic for U.S. policy makers to expect that the Canadian marketplace will not react to and adjust to formal expansion of importation from this country. It's our guess that Canadians would take steps that would further protect their drug supply to avoid shortages and excessive price increases.

NACDS does not believe that legalizing importation is the answer. However, we're committing to working with Congress, the Department

of Health and Human Services, the Food and Drug Administration, and this Task Force to fully explore the issues associated with the importation of prescription drugs.

Thank you, Mr. Chairman.

CHAIRMAN CARMONA: Thank you, sir.

Our next speaker would be Mr. Thomas Ferguson from Treasury.

MR. FERGUSON: Thank you, Mr. Chairman.

I'm Tom Ferguson, Director of the Bureau of Engraving and Printing.

I'm not exactly sure why I'm here.

(Laughter.)

MR. FERGUSON: My level of expertise or area is in prevention of counterfeiting of United States currency.

There is though a great parallel between the two products. Any product which has value, which is seen as an area that can be exploited, will, in fact, be exploited. International counterfeiting of U.S. currency, as well as international counterfeiting of pharmaceuticals is a growing business.

The other area that has a great parallel between the two is that as with currency, it is sometimes easy to provide systems that will

protect the government or the large commercial establishments, but the goal remains to protect the individual, the consumer, to provide that feature or that ability for the consumer to easily and quickly authenticate the product without having to rely on outside technologies.

That goal, that challenge is one that is very difficult to meet. There is no single panacea out there that will provide tremendous total protection every time, in every case.

The other thing that is greatly required if you're going to put in counterfeit deterrent features into product labeling, as with currency, is public education. Putting in great features that are difficult to counterfeit provide very little value if the general public and, in fact, the people in wholesale establishments, as with banks or commercial stores don't know how to use the feature.

The best features are of no value if people don't use them.

I'll be here to answer any questions, but again, anything I can provide, anything we can provide from our experience with U.S. currency is at your disposal.

Thank you.

CHAIRMAN CARMONA: Thank you, sir. Appreciate it.

Next Mr. Robert Bergman from UPS.

MR. BERGMAN: Thank you, Mr. Chairman and members of the Task Force.

My name is Bob Bergman, and I'm with UPS here in Washington in the Government Affairs Office.

As you know, UPS is the largest package delivery company in the world, and we're a major global leader in supply chain services.

I think I'm here because a number of questions have come up about the role of express delivery companies and transportation companies in this issue, and I would say at the outset, as to the fundamental issue that the Task Force is interested in, namely, whether and under what circumstances drug importation could be conducted safely and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients is, frankly, not something that we have a position on or we're going to have a position on.

We're a common carrier, and you know, maybe to will oversimplify, our job is to pick up and deliver packages. Clearly, it's a matter of

interest, and we don't, by the way, you know, carry a lot of pharmaceuticals in terms of our overall business. We pick up and deliver 13 and a half million packages a day worldwide, and pharmaceuticals are not a major part of that.

But we do have an interest, clearly, in this discussion, and any way we can help the Task Force and government regulatory agencies understand how the supply chain works.

Clearly, it is our company's policy not to pick up and deliver illegal products, and we work with law enforcement to insure that our system is not used for illegal purposes. We work on a regular basis with government agencies in their role of screening imports. So we present information to Customs, to FDA, DEA, and any other regulatory agencies, as appropriate.

And just to us as an example, with Customs we have in our major hub in Louisville a state-of-the-art system that we developed for the use of Customs that better enables them to pick out the packages that they want to subject to further screening when they arrive.

We have also, on the related question of Internet pharmacies, have worked with congressional investigators, as well as the DEA and

the FDA, in really trying to identify what is or what should be the role or express carriers in enforcing laws against illegitimate Internet pharmacies.

And in these discussions, we emphasize that we don't have the ability to determine the legitimacy of pharmacies, to determine the legitimacy of a prescription or to judge, you know, the purity of the pharmaceutical itself. Those are simply things that we don't know.

But we have put in place and have had in place for a while a program to monitor Internet sites to make sure that our logo and our name are not being used in conjunction with illegitimate pharmacies. So that's something we do. We take legal action against those where our logo is being used improperly, and we have had discussions, again, with DEA and FDA and will continue to do that in terms of sharing that information.

Clearly, in terms of law enforcement, we have privacy policies that prohibit us from sharing information, but of course, upon proper request and subpoena, we can provide information to help law enforcement agencies identify, you know, whom they need to go after.

I would say in conclusion, and I'd be

happy to answer any further questions, I think our concern in developing any system for importation of pharmaceuticals, that we will clearly comply or develop systems to comply with any conditions that are attached to that, but would caution against trying to put companies like ours in an enforcement role.

We can assist law enforcement, again, but in the part of the chain that we're in, we really have limitations on what we can do in terms of actually being the enforcement agent.

So with that I would be happy to answer any questions.

CHAIRMAN CARMONA: Thank you, sir.

At this point, Panel 1 is concluded. I would like to open the floor to questions from our Task Force members.

Mike, please, go ahead.

DR. O'GRADY: Excuse me.

Mr. Parrish, you talked about the idea of counterfeiting and the relative difficulty of counterfeiting in the United States and outside the United States, and I wondered if you had any further data on what sort of estimates you have in terms of the idea of how big a problem counterfeiting is within the United States, outside

the United States, the United States versus Canada, the United States versus OECD, that sort, so that we can get this feel for the relative level of difficulty.

MR. PARRISH: The specific numbers I don't have with me at this point, Dr. O'Grady, but I have been informed of information FDA has published that indicates that there is an increase in the number of counterfeit activity that has been detected in the United States in recent years.

Similarly, information has been published relative to the counterfeit activity outside the United States and on a relative basis, it has been identified to be greater.

I could bring that information or provide that information to the panel directly, but did not bring that today.

DR. O'GRADY: That would be great. I guess, you know, part of the feeling is the idea that clearly counterfeiting is a serious problem, and it's something that no one wants to ignore, and I just don't have a good feel for the relative, where the United States or Canada. Do the Canadians have a more serious problem than we do, you know, or Third World countries, etc, etc?

One other question. You laid out kind

of I think it was three different kind of key points that would be necessary to be assured of if a notion of importation or reimportation was to be advanced.

Does that mean that if those three were actually accomplished you would be supportive of some notion of importation?

MR. PARRISH: No. Those are the three primary areas that we have concern over. As I stated at the end of my comments, there are additional concerns as well, but I wanted to focus in the limited period of time on the most important issues that we have.

DR. O'GRADY: Okay. Can I ask a question? It's kind of a dual question to both you and to Mr. Stinson as distributors. In terms of even if the difficulties of importation were able to be -- those hurdles were able to be gotten over, do you have any feel for what the kind of net price effect to U.S. consumers would be?

MR. STINSON: I have no direct knowledge of that, but it would be my impression that the price would seek a competitive world market price, and I think that it's going to be a supply and demand situation, and what you're going to find is significant price increases in the

imported product, and probably maybe some reductions, but I think most of it is going to come from the other side. That would be my impression.

DR. O'GRADY: Mr. Parrish, any thoughts?

MR. PARRISH: I believe the answer really would lie in the details of how a system would be laid out. It's a question of the regulatory climate, the legal hurdles, and the economic hurdles that are involved to try to determine what that exact number would be, and at this point I don't think there's enough details available as to how a system would work to be able to give you a number that had credibility.

DR. O'GRADY: Okay. Mr. Julian, I'm very happy to see you here today, given the very unique role that you hold in terms of kind of doing business in this country and Canada and Mexico, and I guess just given that unique situation, do you have a feel of the different products that you distribute through those in all three countries sort of what the overlap is in terms of the kind of dosage and labeling and sort of what is, I guess, the low hanging fruit if one was to think about the importation question, how much that differs between the three countries, or is there a substantial

amount of correlation between the three?

MR. JULIAN: I don't have that type of information just off the top of my head. What I could share with the panel is that what is required in the United States is not necessarily what is required by Health Canada nor the Mexican Health Ministry in terms of the dosages.

So what you would get in Canada is not necessarily for the same product what you would receive in the United States. There are some differences there from a therapeutic standpoint.

DR. O'GRADY: Okay. One last question. Sorry. Also in terms of thinking about your somewhat unique situation, do you have a feel for -- I mean, we normally think of importation as being individuals crossing the border and now a move towards Web based approaches. But given your dealings with large PBMs, large health plans, do you see, do you have any feel for what their reaction would be if all of a sudden there was an opportunity to import drugs from either Canada or Mexico, OECD, any number of different countries?

MR. JULIAN: You know, I think generally speaking, the constituents here in the United States have the same concerns that this panel has expressed in terms of product safety and

ultimate cost savings that could be generated, not to mention just the supply and demand issue. You know, I don't think the Canadian government is going to sit still while they are a tenth of our size and, you know, most of the medications flow back here into the United States.

So I would say that most of the constituents that I talked to here in the United States have similar concerns as everyone here has expressed today.

DR. O'GRADY: Thank you.

MR. JULIAN: You're welcome.

CHAIRMAN CARMONA: Yes, please, Mr. Crawford.

DR. CRAWFORD: Yes. Mr. Julian, you talked about distribution centers on both sides of the border. I assume those would be approved distribution centers, and if so, how would they be designated, in your view?

MR. JULIAN: Well, what I was referring to is I believe for any system to work today you would have to have, due to the supply and demand issues that we will face and we do face today is that you would have to have some sort of closed distribution network that would transfer a product between Canada and the United States. Otherwise I

think the opposition is the borders are so porous it would create a very difficult situation for any of us effectively monitor and then guarantee product safety here in the United States.

DR. CRAWFORD: To follow up, if I may.

CHAIRMAN CARMONA: Please.

DR. CRAWFORD: Who would close the system?

MR. JULIAN: Well, I mean, that is to be determined by you all, I guess, who would close the system if, in fact, you employ a closed distribution system. Our only suggestion is I don't think it can be an open, porous border as it is today and have it be guaranteed patient safety and ultimately some sustainable cost effectiveness that would get to a patient population that is most needy for these types of medications, if in fact savings is generated at all in the final analysis.

DR. CRAWFORD: Thank you.

CHAIRMAN CARMONA: Other questions? Mark.

DR. McCLELLAN: There has been some discussion about supply and demand maybe limiting the extent of savings, of price savings if you could through a large scale importation system, but you all also noted some additional cost that could

be imposed both on the government and on those involved in bringing drugs into the country that might also have an impact on any resulting price savings.

You know, in going back over some of the comments from representatives here who have experience throughout the whole distribution chain for pharmaceuticals, you all brought up issues like making sure that the drugs are FDA approved or somehow equivalent to FDA approved drugs, that there's a track and trace system in place to help assure that the drugs reaching patients in the United States are the legitimate article manufactured by a legitimate manufacturer, and then also issues related to the integrity of the product, that it's stored properly, labeled properly, no other opportunities to introduce safety problems because the medication was okay to begin with. If it's not labeled package, you know, and so forth for consumers properly, then that could introduce safety problems.

Mr. Kocot, you talked about some issues in pharmacy safety practices themselves. So even if the drug reaches a pharmacy intact, making sure that those good pharmacy practices that are required under state laws and regulations in the

United States or followed in these contexts could add costs as well.

None of you put numbers on this though, and one of the things that we're struggling with here is to try to understand, as Congress has directed us to do how much it would cost to set up a system like this, and I wondered if you all cared to add any more detail about the magnitude of the cost impacts or any thoughts on how we could better develop more quantitative estimates of just what it would take to address these kinds of safety issues, issues that are required to make sure that these drugs meet the same standards as U.S. drugs.

MR. JULIAN: Well, I'll take a stab at that, I guess. I think, let me start by just saying that I think it was alluded to in a couple of the remarks here, is that, you know, 45 percent of all prescriptions today in the United States are generics, and the generics in the United States are typically less expensive than they are in Canada.

So that's a huge population of drugs and medications that are already available at a pretty cost effective price.

In addition to that, which you know we should commend the administration today with the Medicare drug bill. We believe that is even going

to enhance the savings that's available in the United States too much of the patient population that is requiring more affordable medications.

Yet in addition to that, I would tell you that foreign manufacturers today offer a variety of programs, patient assistance programs that people that are actually indigent or cannot afford medications are provided to them absolutely free, and they just don't get enough visibility, I think.

And then finally, over the last couple of years, some of the foreign manufacturers have really collaborated and brought out a number of different savings cards programs, like Together Rx and others that, again, have impacted the availability of affordable medications.

Now, going back to your question, I would say that it's very difficult for private industry to speculate on what the actual costs or cost savings would be when there isn't an official model that has been built. It would be purely speculative until, you know, the government in this case would be providing us the guidelines, the rules, the regulations in order that we could go out and build a business model so that we could, you know, clearly articulate to you what the

potential savings might be so that a decision that would be made would be made with facts and not some of the emotion that I think is surrounding this issue today.

CHAIRMAN CARMONA: Other questions? Yes.

MS. CARBONELL: Yes. Mr. Julian --

CHAIRMAN CARMONA: Excuse me.

Mr. Kocot, did you have something?

MR. KOCOT: Yeah, I just wanted to add I don't know exactly what it would cost, but the testing factor that is included in the legislation would be incredibly expensive. Not only that; testing cannot be done in any meaningful way very quickly.

I know the government themselves have gone through testing periods in seizures and have not been able to get tests back for weeks. So to think that we could test and validate lots and supplies of drugs on a regular basis without a lot of cost and the time involved is just going to be absolutely incredible.

I know the manufacturers do have the technology. They do the testing of their own drugs. By and large pharmacies don't. I don't think wholesalers do. Many aspects of the

government don't have testing capabilities.

Testing for drugs, you're looking at really the adulteration. You're looking at impurity. You're looking at strengths. You're looking at storage conditions. You're looking in testing for a variety of different things.

When law enforcement tests, they're looking really at a baseline, as I understand it. Some of you could answer this better than I could, but the point is that there's a lot involved here, and a lot has not been put into practice. So the expenses, as some of my colleagues have said, until you put out a model there and lay a little more specifics on it, legislation has been clear on who would test.

So who has to have this equipment? Who has to put drugs through the rigors? Who has to bear the expense? Those are all questions that we have of you.

CHAIRMAN CARMONA: Thank you.

Josefina.

MS. CARBONELL: You mentioned drug discount cards, Mr. Julian. How would importation impact your Together Rx discount card for seniors?

MR. JULIAN: Well, at this point today, we haven't had any discussions relative to how

importation would affect the drug discount cards. You know, the one that McKesson administers today is the Together Rx program, and at this point that consortium is going to continue to support the Together Rx card through 2006 when the Medicare drug benefit becomes available.

CHAIRMAN CARMONA: Dr. Raub.

DR. RAUB: I have a question for Mr. Bergman.

You mentioned some collaboration with Customs with respect to helping it carry out its regulatory role. Could you elaborate on that?

MR. BERGMAN: Yeah. I mean, we have present in major import facilities, we have a Customs presence. For example, in our major air hub, international air hub, in Louisville, Kentucky, we have on premises Customs Service, and they have always been there to process or to check packages and cargo coming in.

We now have an automated system that we've developed with them to better enable them to check packages that are coming in.

DR. RAUB: Do I assume correctly they're providing the indicia of concerns that's some characteristic of the package?

MR. BERGMAN: Exactly. I mean, the

system that we developed, it really is up to Customs -- I still call them the Customs Services -- it's still up to Customs to plug in any characteristic or indicia. It could be the name of a product or a consignee, consignor, name of a country from which it is shipped, whatever indication, and so plugging it into the system, we can pull out any packages that come from that country or meet that description for further inspection.

DR. RAUB: So by extension, if there were a drug importation schema of some kind and one could provide the indicators about packages that would raise a flag, would it be fair to say that UPS would be able to facilitate that in the same way?

MR. BERGMAN: Yeah. I mean, I think that's right. Assuming, and again, it's all based on how they are identified or labeled, what's declared; what's not declared is clearly a different problem, but whatever is declared can be cranked into the system, and it's now almost completely automated, and so that can just automatically separate out a package and have that go for inspection.

DR. RAUB: Thank you.

CHAIRMAN CARMONA: Yes, Doctor.

DR. WILLIS: Mr. Kocot, you mentioned the importation of individuals of drugs from Canada. Do you have an idea as to the impact on the Canadian pharmacy business as to the extent of the importation currently ongoing? And do you have an estimate as to how it would be impacted both in Canada and in the United States if we did allow an importation of drugs?

MR. KOCOT: IMS has estimated that about four percent of the Canadian market is coming to this country. However, we've seen a lot more evidence that that number is even greater than that. We're seeing more and more businesses springing up. The thing that scares us most is that many of those businesses purport to be Canadian businesses, but they're either not operating in Canada or they are selling drugs that are not from the Canadian system.

Last Friday, a group in Manitoba exposed two such sites that were selling drugs through Canada from Mexico and the other one was selling them in Vancouver through the U.K.

Right now estimates are that in Manitoba alone about 40 percent of the drugs are being diverted to the United States. Manitoba is

probably the largest diversion point, but that's substantial for one province.

We understand that that number may be as high for some categories of drugs. For example, it could be as high as 60 percent for heart medication. The numbers are astounding when you look at what is happening in parts of Canada.

CHAIRMAN CARMONA: Alex.

MR. AZAR: Sorry to bother Mr. Julian again, but I think given the nature of your business with its international scope you might be best able to help on this, but any of the others who might have knowledge of the chains of distribution in other countries I'd appreciate your thoughts.

The question really is what is your sense in terms of managing the risk of importation, what the factors are that we should be looking at and what the differences are, for instance, in -- the risk factors among different countries of origin for importation, different systems of distribution in other countries, how safe they are, whether some present greater risk, some lesser risk; the issue of manufacturing facilities in different countries, which are safer, which are less safe; and also whether the type of product,

biologic, pharmaceutical, do they present different risk profiles for an importation question?

MR. JULIAN: Well, you know, I can only speak for North America, and I would say that the United States' health care system is by far and away the safest. I would say also I believe the Canadian health care system is a very safe system, yet I would say it is geared for the Canadian marketplace. It is not to address exported material to the United States or anywhere else.

Since we have a presence in Mexico, I think Mexico has a long way to go to catch up to either the United States or Canada in terms of their safety and regulations.

I would also just add that the more complicated the product, the more difficult it is in order for you to make sure that you've got the right product with the right dosage, therapeutic equivalency and everything else made in other parts of the world.

CHAIRMAN CARMONA: I'd just like to ask a general question, especially to those involved with the importation, but all of you please feel free to ask.

Your sense on how sustainable a national health policy of importation would be to

remedy the problem both in the short term and in the long term.

MR. PARRISH: I think that's a very difficult question to answer. I would think that it's going to be driven primarily by unfortunately many economic concerns as well as public policy concerns. The availability of supply will be in many ways the major issue from the standpoint of how sustainable this particular type of activity will be.

And contained within that availability of supply issue is the question of the length of period that the spread, if you will, continues to exist between the countries. I think even if a system is able to be put together, and there certainly are issues that can be addressed to put a system together in the short term, that system will have to be responsive to the longer term changes in the costs between the different countries to be able to continue to offer benefit to the consumers for whom the product is available.

It's very much a moving target and a very difficult situation to deal with, but I think the spread is a very important piece to keep in mind as you address this issue.

CHAIRMAN CARMONA: Thank you.

Anybody else care to comment?

MR. SACHDEV: I had some questions.

CHAIRMAN CARMONA: Do you have a question as well? Please.

MR. SACHDEV: I did. It's for Mr. Parrish.

Mr. Parrish, your testimony focused on some key points in terms of authentication and integrity of drugs. My question relates to your points about testing because that's an issue we thought about. If you really want to do authentication and look at integrity, one way to do that is testing, but if you look at your recommendation, it seems like it would be fairly expensive to test every product, every batch, every lot, which is, I think, what I heard you saying.

Do you have any estimates of what that might cost, putting aside whether it is the government that would be paying that or a distributor or the manufacturer?

MR. PARRISH: Speaking on behalf of, in answer to this question, Cardinal because we do have contract testing and analysis companies as part of our portfolio companies, I can get you some specific information, and we would be happy to provide that to the panel relative to the cost of

testing.

My comments refer to the need to test each lot for every individual product. I'd like to just clarify that. We're not talking about testing every single bottle. That would be absolutely cost prohibitive.

We're talking about samples from within each lot that comes through. But, again, the issue with counterfeiting, the issue with adulterated product is it tends to be very random, and the people who engage in this type of behavior, once they understand what the testing protocols are, will more than likely find ways to work around them.

So the testing will be effective, but it will not be a guarantee.

MR. SACHDEV: Another question for both Mr. Julian and Mr. Parrish.

You both spoke about the need, in considering importation, to restrict importation or limit importation to essentially the FDA formulation or the FDA approved product. That's certainly something that we've been tasked to look at as we consider legislation that actually potentially goes beyond that.

You've both talked about the need for

good authentication. Are there particular authentication technologies that you guys are currently looking into as distributors? And in fact, can you tell us about their feasibility with respect to drug importation?

MR. PARRISH: I'll take the initial crack at that.

From the association's standpoint, we have been very vocal in favor of the Auto ID testing and the EPC product code identification. However, that is a technology that is still in its infancy. It is a technology that has great promise. We are involved in many tests and demonstration projects right now, attempting to show the efficacy of this type of identification technology, and it's a little too early to tell just how well it will work, but again, it shows great promise.

And it is far too early to tell what the cost of this technology will be.

MR. JULIAN: I would just echo everything that Mark just said. The only point I would add is that we're extremely hopeful that the track and trace technology of the auto ID EPC technology will work. There is tremendous momentum regarding track and trace technology with worldwide

manufacturers, and quite frankly, in order for it to work, it has to emanate with the manufacturer.

CHAIRMAN CARMONA: Any other questions from the Task Force members?

(No response.)

CHAIRMAN CARMONA: If not, I'd like to thank the panel for coming and joining us today and providing us with the information.

We will turn over to the second panel right now. So everybody just take a quick stretch break, and we're going to keep moving right through.

Thank you.

(Whereupon, the foregoing matter went off the record at 3:08 p.m. and went back on the record at 3:14 p.m.)

CHAIRMAN CARMONA: Hi, ladies and gentlemen. Thank you for joining us.

And we will begin first with Mr. Bruce Downey from Barr Labs. Is he here? No? I saw papers.

Okay. Well, let me move then over to Mr. Howell and we'll come back. Okay. Thank you, sir.

MR. HOWELL: Thank you, sir. Thank you for having us today.

My name is D.W. Howell, II. I'm the Director of Global Product Protection for Eli Lilly & Company.

The Global Product Protection Office of Lilly was formed in January of 2003 to intensify our ongoing anti-counterfeiting efforts regarding Lilly products.

Prior to 2003, I was Lilly's Director of Global Security for 20 years. Before that I was an FBI agent for 11 years in various field assignments. My testimony before your Task Force is focused on the increasingly sophisticated activities of counterfeit pharmaceutical networks that pertain to Eli Lilly & Company products, but let me be clear. By "sophistication," I'm not referring to the quality of the knock-off ingredients, but instead the highly developed packaging and printing replication capabilities used to mimic the approved product, their increasing anonymity afforded by the Internet, and their intricate and quick responding distribution networks.

In the last several years, we have noticed an increase in the counterfeiting of Lilly products. Counterfeits today are being sold through complex distribution networks with

packaging that is often indistinguishable from our own even by experts.

With the advent of the Internet, a whole new era of counterfeiting has begun for us. It is now feasible to rapidly distribute counterfeit products with relative anonymity. We have identified several criminal syndicates who now manufacture, package, and distribute counterfeits on a global basis. These syndicates deal in illicit drugs and receive funding from identified organized criminal elements.

We have been advised by law enforcement entities that in some instances these syndicates are linked to terrorist organizations in the Middle East, Afghanistan, Pakistan, and to some drug cartels in Mexico.

In many cases, counterfeits are produced in facilities in China and then distributed to Korea, Taiwan, and surrounding countries for packaging and distribution. These syndicates often manufacture knock-offs in filthy, unsanitary conditions. Importantly, these products don't stay in Asia. They travel to major Western pharmaceutical markets. We've bought with us some photographs of these conditions.

As part of our investigative process,

we have tested these knock-offs, and we find a range of potential safety concerns. In some cases the product is subpotent. In others it's super potent or mixed with other active ingredients or with unknown substances.

In other cases these counterfeits contain no active ingredient at all. In some cases the chemical composition is similar to our own.

We believe all of these scenarios raise significant safety issues because the counterfeits are produced in unsanitary conditions with absolutely no regulatory oversight.

I'd like to walk through some recent counterfeit investigations of Lilly products that we've recently encountered.

In one case, with the cooperation of Taiwanese authorities, we identified an illicit drug ring in Taiwan that was producing counterfeit Lilly product on the same machines they were producing counterfeit methamphetamines or methamphetamines. Excuse me. We have photographs of some of these products.

In a different case, counterfeit Lilly product originated in China and was moved through Korea and into the Middle East. In this instance, Israel authorities discovered the operation.

Subsequent raids occurred in Israel locations in the last several weeks that were producing counterfeit packaging to contain these Chinese originated counterfeit tablets for distribution within Israel.

In another case, we recently detected Lilly product coming in from China. It was moving through Belgium disguised as a shipment of computer parts destined for the U.K.

In 2003, we along with other companies, federal and local law enforcement participated in some raids in the Los Angeles area of a Vietnam based organization that was importing counterfeit pharmaceutical products from Canada into the U.S., including Zyprexa, a Lilly product for schizophrenia and bipolar disorder.

In this case, the counterfeiting was twofold. This operation stripped our Zyprexa out of its legitimate packaging, filling the original bottle with iron tablets, and distributing these bottles for consumption outside the U.S.

As a second step, they placed legitimate Zyprexa tablets into counterfeit bottles for consumption in the U.S. marketplace. The counterfeiters mixed multiple strengths of Zyprexa in the same bottle before sending them out to

secondary U.S. distributors.

As you can see from these examples and the type of activities I've described, we have significant concerns regarding counterfeit syndicates and the flow of product into the U.S. from Canada, the Internet, and other illegal and unsafe distribution channels.

Finally, I can also report that our company has received patient or physician initiated reports in the U.S. of instances where a drug alleged to be Lilly product was purchased from Canada and resulted in patient harm. In one case, a diabetic patient experienced adverse events after taking insulin that was improperly stored and shipped or was past the expiration date. This patient ended up in a coma.

Keeping in mind my testimony is based on today's environment, which is relatively closed in the U.S., our supply is FDA approved and the distribution channels are straightforward and transparent. We can only imagine the impact of these highly involved counterfeiting rings, the impact they could have in a world where drug importation was legalized.

Thank you.

CHAIRMAN CARMONA: Thank you, sir.

Our next speaker will be Mr. Bruce Downey.

Thank you, sir.

MR. DOWNEY: Thank you, Mr. Chairman, and thanks to the members of the Commission for inviting me to testify today.

I have submitted a written statement that covers more comprehensively the subjects I would like to take up in my remarks, but I do want to emphasize a few of the points that are in my written testimony and respond to some of the questions I heard asked to the first panel, to the best of my ability.

I am Bruce Downey. I am the Chairman and CEO of Barr Laboratories. We manufacture and distribute over 100 pharmaceutical products, mostly generic, but a few brand products as well, and I'm happy to give you the reasons why we oppose relaxation of the importation standards of products into the United States.

Our market here is a very dynamic one, and it is really defined by four public policy decisions that have been made by the Congress and the regulators in this country. The first is a comprehensive system of regulation to insure the safety of pharmaceutical products.

Second, strong patent protection to stimulate innovation of pharmaceutical products.

Third, a set of additional exclusivities beyond the patent laws that reward companies for pediatric research or for introducing a new chemical entity in the United States, doesn't have patent protection or restore market exclusivity lost in FDA review time, again, to insure adequate incentives for innovation in the pharmaceutical industry.

And, finally, although there has been a great deal of debate, we have a free market in this country, one that is not defined by price controls. Price controls have been specifically rejected, and we believe that these fundamental principles which have been established in wide public policy debate shouldn't be compromised in any way by importation of products into the United States.

If companies want to compete here, they should live by our rules, and they should be welcome to compete on that basis. Anyone who really suggests that we modify these rules is arguing that we should compromise these very significant principles. In essence, we would be exporting our public policy decision making to Canada or to some other country, and importing the

results of that decision.

We think if we want to change the rules, it should be done in the United States in our open society, and a debate before the Congress or the appropriate regulatory officials where we would do straight up what we don't want to do by importing something from another country that is someone else's decision.

I also think that the benefits that people have argued for this importation rule have greatly been overstated. We point out some examples in our written testimony, but let me just give you a couple of them.

The proponents of the principal House and Senate bill that would establish this importation policy contend through enactment of the legislation with, say, $560 billion a year, that's a very interesting number considering the entire U.S. market is only $214 billion a year. I think that sort of exposes the kind of thinking that's going into some of the proposals that have been advanced.

We also point out in our written testimony some of the studies used to support the legislation that impose importation rules are flawed. For example, in suggesting the price of

ciprofloxacin, a very important product in Germany, they ignore the 16 percent value added tax in that country. They ignore the cost of having the product sent from Germany to the United States, and there are similar flaws in a lot of the examples that were used in these different studies.

Also it's important to know that importation in my judgment would very much harm the generic industry, which is the strongest cost cutting instrument available in the United States. If you look at countries that have price controls, you find that the generic industries in those countries aren't nearly as robust as they are here. There's very diminished incentive to be the first to the market, and our generic industry has resulted in enormous cost savings to the United States that some of the prior panelists said our costs in the United States were much lower than they are in Canada.

And I think that any decision that would reduce the incentive to go into the generic business would reduce the generic R&D programs just as it would the brand R&D programs.

In addition to the overstatement of the benefits of an importation bill, I think the safety concerns haven't been adequately addressed. We

have heard some of the concerns about non-NDA, non-ANDA products. Again, I think that's the gold standard in the world. We shouldn't compromise our system by allowing products that don't meet those standards to be introduced in the commerce of the United States.

And it's also true that as you allow more importation, you increase the opportunities for counterfeiting. Mr. Howell pointed out that's a very serious problem and one that I think would be exacerbated by reducing the barriers from bringing products in from Canada from other countries, and I would, again, on the basis of safety think that would be very unwise.

And finally, I think for the overall public health effect it would reduce innovation and reduce the incentive to pour billions of dollars into research and development with an uncertain opportunity to recover those investments. Again, over a long period of time that reduction in R&D, I think, would have a very negative impact on the health care system of the United States and one that we should be very careful before we do anything about it.

CHAIRMAN CARMONA: Thank you, sir.

Our next speaker from Pfizer, Mr. John

Theriault.

MR. THERIAULT: Thank you, Mr. Chairman and distinguished members of the Task Force.

My name is John Theriault. I'm Vice President of Global Security at Pfizer, and it's a pleasure to appear before you today to discuss an issue of critical importance, protecting the U.S. pharmaceutical supply from contamination by counterfeit and unapproved generic products.

Prior to joining Pfizer, I spent 25 years as a special agent of the FBI. During my FBI career, I had substantial experience in international law enforcement, having served for a number of years as the legal attaché in Ottawa, Canada, and in London, England.

I retired in 1995 as a member of the Bureau's Senior Executive Service.

Pfizer is a diversified global health care company and the world's largest pharmaceutical company. Our annual pharmaceutical sales are more than $40 billion, and we have 122,000 employees around the world. Our core business is the discovery, development and marketing of innovative pharmaceuticals for human and animal health, and we are committed to insuring the integrity of those products when they reach the market.

Mr. Chairman, while my testimony today focuses on our experience with counterfeit Pfizer products, I wish to impress upon the Task Force that these problems are not limited to Pfizer. They threaten the entire research based pharmaceutical industry and the U.S. consumers who depend upon that industry.

I'd like to start by addressing the issue of counterfeit pharmaceutical products and the scope of the problem. It's wide accepted that China and India are major sources of counterfeit pharmaceutical products found throughout the world. Prior to 1998, relatively few of those counterfeits found their way into the United States or other countries with strong pharmaceutical regulatory systems.

It was commonly believed that counterfeits were a problem primarily for less developed countries. However, in 1998, we discovered counterfeit Pfizer products in the United Kingdom. The problem has grown consistently since then, and today we see counterfeit Pfizer products throughout Europe, the Middle East, Asia, Africa, and the Americas.

Pfizer counterfeit products have been found in each of the EU member countries, as well

as in eight of the 15 candidate countries. Australia, Israel, Japan, New Zealand, Norway, Switzerland, and South Africa are also among the countries where counterfeit Pfizer products have been detected. Seizures in the Asia Pacific region have included counterfeit packaging not intended for local markets, but rather for export to the U.S. and Australia.

A disturbing trend has emerged in Asia. While seizures of counterfeit Viagra tablets dropped from more than 1.8 million in 2002 to about 760,000 in 2003, seizures of counterfeit Norvasc, a major cardiovascular medicine increased from fewer than 4,000 tablets to more than 1.5 million during the same period.

Even with the realization that counterfeits are so widely available, there's a tendency to believe that they're distributed only by illicit brokers or the unregulated pharmacies that have become so common with the Internet. The implication is that legitimate channels of distribution in countries like the United States are largely immune to the dangers of counterfeits.

Unfortunately, the facts are otherwise. A case in point, counterfeit Lipitor. Lipitor is indicated for high cholesterol and is the most

prescribed medicine in the world. During 2003, almost 69 million prescriptions for Lipitor were written in the United States alone.

Any notion that even the current strict regulations in the United States provide adequate safeguards against the importation of counterfeit and unapproved pharmaceuticals should have been dispelled with the recall over more than 18 million Lipitor tablets beginning in May of 2003. Those tablets, a combination of counterfeits and legitimate product of undetermined origin, had been repackaged by a company called Med-Pro located in Nebraska and distributed primarily by Albers Medical of Missouri.

The counterfeits first came to light as a result of a consumer complaint that the tablets tasted better and dissolved too quickly in the mouth. Tablets provided by those consumers were tested and found to be counterfeits containing Lipitor's active pharmaceutical ingredient.

The FDA was notified in April and launched an investigation of both Med-Pro and Albers. Pfizer continued to notify the FDA as more counterfeits were confirmed.

In May and June of 2003, Albers issued three recalls of Lipitor, ultimately recalling all

of the Lipitor that had been repackaged by Med-Pro. According to the Commissioner of the FDA at the time, those recalls totaled more than 18 million tablets.

To put that number into perspective, more than 600,000 U.S. residents, after visiting their local pharmacy or placing an order with their health plan either by phone, mail, or on the Internet, may have received a 30-day supply of Lipitor that contained counterfeits.

While the Med-Pro/Albers recall was the largest, it was unfortunately not the only incidence in which counterfeit Lipitor was repackaged and introduced into legitimate distribution channels. There were at least two other instances in which firms that had repackaged authentic Lipitor that they had illegally diverted from foreign markets, began the far more lucrative practice of repackaging counterfeits.

In one such case, Lipitor tablets repackaged by a company called AQ Pharmaceutical of California were found to be counterfeits matching the same Med-Pro formulation. As a result of an investigation jointly conducted by the FDA and the Los Angeles County Sheriff's Office, it was determined that AQ and two related companies were

importing authentic Pfizer products from foreign markets, repackaging them, and then illegally selling them in the United States. The principal Pfizer product being repackaged was Lipitor obtained primarily from Canada.

When search warrants were executed at those firms in February of 2003, authorities seized large quantities of Pfizer products, including Lipitor. While some of those products were still in their original packaging, others were in zip-locked bags with handwritten notes identifying the product, lot number and expiree dates.

One of the companies affiliated with AQ was licensed and registered to import pharmaceuticals for export, as well as to repackage pharmaceuticals. It was later discovered that that company, in order to create the appearance that the products it had imported actually has been exported, filled the empty pharmaceutical bottles with vitamins and then exported those misbranded bottles to a hospital in Vietnam.

Investigation into these cases revealed that the counterfeit Lipitor in question had been manufactured in Costa Rica with API imported from Switzerland and excipients and tooling imported from the United States.

It is generally accepted that product diversion and counterfeiting often go hand in hand. The simple fact is that the more times a product changes hands, the more difficult it is to authenticate its pedigree and the easier it is to introduce counterfeits. These are particularly illustrative of that fact.

The FDA's finding in these investigations as disclosed in the affidavit filed in support of a criminal complaint against one of the subjects was that each bottle tested from a particular lot was found to contain a commingling of both legitimate and counterfeit tablets.

Cross-border sales. The facts today indicate that the major threat to the U.S. pharmaceutical supply is not from within the U.S., but rather from other countries, including our neighbor to the north. An incident recently reported to my office demonstrates our concern with the integrity of the pharmaceuticals available through Canadian Internet sites.

An elderly woman in California living on a fixed income placed an order with a Canadian Internet site, Rx Value Canada. Although the site offered several generic and unapproved alternatives to Norvasc, she chose a product that was

specifically identified on the Web site as Pfizer Norvasc produced in the United States.

When her order arrived, however, it had been filed with Norvasc in Russian packaging. Although the product was tested and found to be authentic Norvasc, it demonstrates that those who order pharmaceuticals from Canadian Web sites do not necessarily receive products that have been manufactured in Canada or in any other country from which importation would be authorized.

In this instance, the consumer was fortunate, but the question remains whether other consumers placing orders from Canadian pharmacies unable to meet the increasing U.S. demand would be so lucky.

CHAIRMAN CARMONA: Would you sum up, please, sir?

MR. THERIAULT: Yes, sir.

Clearly, there is already importation of counterfeit and diverted products into the United States through the mail, courier service, and unethical repackagers and wholesalers. The existing strict regulations are ineffective in preventing it, and the issue right now should not be, in my opinion, discussing ways to deregulate the current safety system, but rather to discuss

ways in which the current system can be improved and better equipped to deal with this growing threat.

Thank you, Mr. Chairman.

CHAIRMAN CARMONA: Thank you, sir.

Our next speaker will be Mr. John Dempsey from Johnson & Johnson.

MR. DEMPSEY: Mr. Chairman, members of the Task Force, Mr. McGinnis, thank you for giving Johnson & Johnson the opportunity to participate in the review of this critical issue of whether drug importation in the United States can be conducted safely.

I'm here to talk about Johnson & Johnson's experience with counterfeit drug in the marketplace because we believe that any drug importation program would greatly increase the number of such counterfeit products putting Americans at unacceptable risk.

From all indications, the problem of counterfeit health care products is growing. According to the FDA, its counterfeit drug investigations have increased from over 20 a year, sine the year 2000, a sharp increase from the average five per year in prior years.

FDA has initiated 73 counterfeit drug

investigations sine October of 1996, the majority in the last two and a half years, netting 44 arrests, 27 convictions, with the number of criminal investigations still ongoing.

The Pharmaceutical Security Institute's 2003 situation report states that there was a 60 percent increase in the incidence of prescription drug counterfeiting in 2003. They have documented 264 incidents of counterfeiting in 2003.

Unfortunately, like several other health care companies, we experience the impact of counterfeit drug in the marketplace. The first known instance was Procrit. The second was a medical device, and that was the first time a medical device had been counterfeited in the marketplace today, and it was a surgical mesh product whose origin was from outside the United States, but entered into the ethical supply chain within the United States.

Our widely prescribed amnesia drug, Procrit, which is used by patients with cancer and also patients with HIV disease, has been the target of counterfeiters and patient safety was put at risk.

The information we present here today is informed by the experience of having had to deal

directly with threats to the health and safety of the people who depend on the integrity of our products and the ability of the FDA to monitor the manufacture and development of such products.

The counterfeit drug labeled as Procrit was first discovered in May 2002 at a large drug wholesaler. Sine that initial discovery, investigators found the counterfeit product was shipped from two of the three largest national wholesalers and was also found at various retailers across the country.

Two separate operations were uncovered. One operation relabeled 2,000-unit product as 40,000-unit product. The counterfeit product looked identical to the real product. Vulnerable cancer patients being treated for anemia could have received the product that was 20 times less potent than what was prescribed for them originally.

The second operation produced counterfeit product vials filled with distilled water that contained bacteria. Again, the vials looked identical to the authentic product. In this case, patients could have received contaminated water instead of the drug that had been prescribed to treat their anemia. It is believed that the FDA and the Office of Criminal Investigation was able

to stop this operation before any of the product reached patients.

As a result of these incidents, we have taken significant measures to increase our efforts to prevent counterfeiting, taking steps to safeguard the distribution chain and using state-of-the-art technology in our packaging to make it more difficult to copy.

Legislative proposals that would throw open our borders to drugs that vary in any way to FDA approved drugs and that would require partial or no FDA inspection of foreign production and packaging lines would simply enable counterfeiters to contaminate our drug supply earlier in the process, not just at the distribution chain level, which would further undermine any anti-counterfeiting technology we invent.

We have enough challenges with the closed regulatory system today at the distribution chain level in terms of counterfeiters infiltrating our system. The solution is not to further open our system to foreign lines of production and packaging that is outside of FDA's oversight inspection and enforcement authority.

Johnson & Johnson's pharmaceutical group has been investigating and implementing any

counterfeiting technology for several years now. These technologies fall into two broad areas. Authentication technology builds certain overt and covert features into the packaging to enable identification of counterfeit product. Track and trace technology, which has been the subject brought up by many of the previous panel members, allows for electronic tracing of shipments and even individual product units.

Authentication technologies fall into three groups: overt, which is visible to the naked eye; covert, which is not visible to the naked eye and has to have some type of hand-held reader; and then forensic, which requires a sophisticated lab to authenticate built in anti-counterfeiting technologies into the packaging.

The track and trace technology that has received the most attention is radio frequency identification attacks. Johnson & Johnson is studying the use of RFID technology as part of its total anti-counterfeiting arsenal. To that end, we have been active in the Accenture Jump Start Initiative to test the feasibility of RFID technology.

And the technology has two separate applications. The first is an anti-counterfeiting

mechanism. The second is a broader application for use within the supply chain.

From an anti-counterfeiting perspective, this technology, we hope, would allow us to get ahead of the counterfeiters somewhere between 12 to 18 months. Authentication could be done with hand-held readers by field-based personnel, but the technology is at least, at least 18 to 24 months away from full implementation. It does not protect us from product entering from outside the United States over the Internet. In fact, in order to completely safeguard our system, we'd literally have to put readers in the hands of every end user. As long as there's an opportunity to make money, counterfeit drug will continue to be an issue.

RFID would make our current regulated system safer, but it's not failsafe. It doesn't provide safeguards for product purchased over the Internet or product ordered overseas and shipped through the mail.

The second application of RFID within the supply chain is at least five to ten years away from full implementation, and only if the price comes down on the chips and the antenna.

We have taken a number of steps in the

packaging of pharmaceutical products that will enable us and our customers to more easily detect counterfeit products. By the end of this year, all of our major pharmaceutical brands representing approximately 80 percent of sales will have one or more anti-counterfeiting features built into the packaging.

In conclusion, we believe that importation is neither a panacea nor a long-term solution to our country's need for meaningful and affordable prescription drug coverage within health insurance. We look to Congress and the FDA to continue to devise appropriate solutions to insure that any medicinal products brought into the U.S. continue to pass the same stringent safety requirements of products currently made and approved for distribution here.

I guess I'd like to close with one final statement. You certainly can listen and take in everything that the panel members say and provide you with the information about the different technologies that are available.

I think it's also important that you poll the people that work for you in the Office of Criminal Investigation and ask them what their opinion would be if we were to open our borders up

to 25 industrialized countries across the world. I think that their comments would be in line with our comments in that it would strike great fear in our abilities to be able to protect the American public.

Thank you.

CHAIRMAN CARMONA: Thank you, sir.

Our next speaker, Ms. Pamela Williamson from Serono Labs.

MS. WILLIAMSON: Good afternoon. My name is Pamela Williamson-Joyce, and I'm Vice President of Regulatory Affairs and Quality Assurance for Serono.

Serono appreciates the opportunity to provide comments to the Task Force on Drug Importation.

Serono is a global biotechnology leader, and in addition to being the world leader in reproductive health, Serono also has strong market positions in neurology, metabolism, and growth. The company's research programs are focused on growing fees, businesses, and on establishing new therapeutic areas.

You'll hear some similar themes to my comments as you have from my colleagues here at the table this afternoon.

Serono believes that changes to regulations governing drug importation or reimportation have a significant potential to increase safety risks for patients and consumers due to the increased drug diversion and entry of drugs that are counterfeit into the U.S. market.

Any perceived or potential cost of savings for U.S. consumers would be far outweighed by the potential cost to patient safety, product integrity, and confidence in the U.S. drug distribution system.

During 2000, Serono detected what was confirmed later to be a counterfeited version of one of its products, Serostim. Serostim is a recombinant human growth hormone indicated for the treatment of HIV patients with wasting cachexia (phonetic), and it's administered by subcutaneous injection. As part of its usual product support services, Serono has a quality assurance group that, among other responsibilities, receives, processes, and initiates investigations of any technical complaints regarding its products.

It's this group that in late 2000 received the first calls that alerted the company to the potential existence of counterfeit product. Callers reported that the vials of diluted, which

is the sterile water for injection that is mixed with the active drug ingredient, appeared to be slightly under filled. A few of the callers also reported some stinging and burning at the injection site for one particular lot number.

Per our usual procedures, replacement product was provided to the patients through their pharmacies, and we asked that the suspect product be sent to us.

Upon receipt and visual inspection of this material, it was determined that the questionable product was not Serono's product at all, but rather a counterfeit product labeled and packaged to appear as Serostim. The counterfeit material made its way into the U.S. retail drug distribution system, including your neighborhood pharmacies.

Serono immediately notified the FDA's Office of Criminal investigations and numerous discussions with various offices with FDA at the local, regional, and federal levels followed.

Serono also on its own initiative alerted pharmacists and drug wholesalers to the counterfeit material and recommended that they examine Serostim prior to dispensing to see if it had a particular lot number or expiration date or

other identifying features of the counterfeit material.

We also informed physicians prescribing Serostim and AIDS services organizations. We also included press release on our Web site, as well as FDA's Web site.

But because individual patient information is not available to companies, we could not conduct any outreach to patients directly.

In total, Serono has experienced three discoveries of counterfeit Serostim material. The unusual circumstance with this product prompted the company to design a program that would secure the integrity of Serostim without jeopardizing patient access.

The system is designed to tighten control of distribution, to detect the entry into our distribution system of counterfeit or diverted product, and to allow for the tracking and tracing of each individual box.

Serono undertook an intensive process of designing what is known today as the Serostim secured distribution program, making changes within manufacturing to add an additional bar code to the product, including a unique numbering system for each and every box of Serostim.

In October 2002, this program was rolled out through the distribution chains and to increase assurance that consumers who were prescribed Serostim received the genuine FDA approved product. With its tracking of each prescription size packet of Serostim through a controlled smaller network of pharmacies, the program provides deterrence and valuable intelligence for use in prosecution of those individuals who may attempt to misuse or misdirect the product.

Serono has, in fact, responded to many requests from law enforcement to utilize the tracking and tracing capabilities, to provide information for use in ongoing investigations.

Serono also periodically monitors the Internet for Web sites mentioning Serono products. From time to time we have identified illicit Internet activity related to our drugs where on-line pharmacies are not appropriately licensed and are not in compliance with state and federal pharmacy laws. Various of these Internet pharmacies claim to offer Serono products. Yet they are outside of our distribution system and often these products are not what they are purported to be.

We have issued cease and desist orders and have alerted the FDA Office of Criminal Investigations as to our concerns about these particular Web sites. In one example of illicit Internet activity in 2003, Serono discovered that Serono products were being offered for sale on eBay. It is not possible to confirm whether products are genuine based on information posted.

Serono contacted eBay's General Counsel to request the immediate removal of the posting. eBay removed the listing for violation of their own policy prohibiting the sale of prescription drugs, and ultimately agreed to use technology filters to prefer further posting of Serono products.

Serono does everything within its reasonable span of control to assure patient safety and product integrity and these additional steps have been taken at our own initiative.

However, no such programs can be considered foolproof. Serono believes that loosening restrictions on drug importation from foreign sources would hinder our ability to carry out track and trace programs, such as the one that we now have in place for Serostim.

Our program is focused on safety and security within the U.S. Opening the borders to

importation of products intended for distribution elsewhere would render the program ineffective. Change in current practice also changes the dynamics of drug distribution and raises new incentives for illegal activities.

The American public relies on the U.S. Food and Drug Administration (FDA) to insure that the drug products in the U.S. are proven to be both safe and effective. The subsequent maintenance of these drugs, monitoring and post marketing reporting, as well as security of the distribution and supply chain are also of critical importance.

FDA's standards for demonstration of safety and effectiveness are rigorous, with numerous regulations covering the vast aspects of drug development and registration, including the conduct of clinical trials in humans, processes and facilities for product manufacture and testing, product storage and therapeutic labeling claims, and instructions to physicians and patients which provide important information on the risks, benefits, and use of any particular drug.

Such standards for product approval and maintenance differ from country to country, as do the mechanisms for distribution of product through the respective supply chains.

Although attempts are underway to harmonize certain technical components of product registrations through the International Conference of Harmonization, the reality is that there is no common standard for judging the safety and effectiveness of products on a worldwide basis.

In fact, it is not uncommon for major health authorities to disagree on the approvability and/or labeling or drugs. We urge Congress and the administration to maintain current policy and take steps to increase surveillance of commerce and prescription drugs originating from foreign sources.

I'd like to thank the Task Force for the opportunity to provide these comments, which we hope will be helpful in your deliberations.

CHAIRMAN CARMONA: Thank you very much.

Our next speaker, Captain Gordon Johnston. Welcome.

MR. JOHNSTON: Thank you, Mr. Chairman and members of the Task Force.

My name is Gordon Johnston, and I'm the Vice President of Regulatory Affairs for the Generic Pharmaceutical Association, and I'm the former Deputy Director of FDA's Office of Generic Drugs.

On behalf of GPHA and its more than 140 members, I thank you for the opportunity to speak today.

GPHA is here today because we share in the public's concern about access to affordable medicine. FDA approved generics account for more than 51 percent of all prescriptions filled in the United States. Yet generics represent less than eight cents of every dollar consumers spend on prescription drugs.

We believe that any long-term solution to high prescription drug costs must not sacrifice safety or quality of our medicines. Thus, GPHA opposes the importation of pharmaceuticals that have not been under the regulatory oversight of FDA. If we permit the importation of unregulated prescription drugs, drugs that have not been FDA approved, we will, in effect, abandon the free market principles that we have been so instrumental in allowing the generic industry to provide cost effective prescription drugs.

More importantly, importation without adequate safeguards could shred the fabric of FDA's safety net that has protected consumers from the entry of unregulated drugs of questionable safety, potency, and quality for more than 70 years.

Today there's no system to determine whether imported drugs that are not FDA approved meet the basic quality standards or whether they are subpotent, improperly labeled, contaminated or counterfeit.

Simply put, unless and until FDA has sufficient oversight over all drug importations and the necessary resources to enforce such oversight, the nation's drug supply is vulnerable to the influx of inferior and/or potentially dangerous medications.

Furthermore, the cost savings the proponents suggest will come from importation of drugs that are not FDA approved are questionable at best. Several reports suggest that on average U.S. generic drugs are more affordable than Canadian generics. Indeed, it seems counterintuitive to permit the entry of unregulated imports if there is a less expensive generic already available to consumers here at home.

At a minimum, unregulated prescription drug importers should be required to establish that the proposed imported product has no lower cost generic equivalent approved in the United States.

Equally important, unregulated importation ignores the cost to consumers of

undermining the 180-day generic exclusivity incentive, an incentive that is key to bringing consumers accelerated access to affordable medicines.

In addition, importation ignores the potential costs associated with the medical treatment of consumers who have obtained poor qualities that don't work or subpotent or toxic. It also ignores the cost of treating consumers taking unregulated and imported drugs that are improperly labeled or not stored under proper conditions during shipment. And one of our other speakers mentioned that as an example today.

Lastly, we have yet to determine the costs to FDA approved imported drugs of implementing an import program for the non-FDA approved drugs, whether an importation system would impose additional needless requirements or result in a negative impact on the availability of FDA approved imported drug products.

Additionally, we cannot predict how the cost of such an oversight program will impact the future availability of FDA approved generic drugs or the generic drug industry in the United States.

GPHA believes that the solution to high prescription drug costs will not be found in

unregulated foreign imports, but rather greater utilization of FDA approved generic prescriptions. There are tools available that help immediately increase generic utilizations and savings, such as educating consumers, physicians, and states about generic availability, encouraging generic substitution, employing benefit designs to incentivize the use of generics and insuring their timely market entry.

FDA plays an important role in assuring that American consumers have access to generics. Yet its Office of Generic Drugs will receive no additional funding this year. Meanwhile the number of generic drug application continue to grow.

Congress and the administration need to increase the resources necessary to approve generic drugs more efficiently and make generic approvals a priority rather than creating an expensive new regulatory scheme to monitor the importation of unregulated drugs.

Congress and the administration must also focus on establishing a definitive approval process for generic versions of biopharmaceuticals. Last year biopharmaceuticals cost payers more than $21 billion. Generic versions of these products would save billions of dollars each year.

As Congress and the administration consider importation of unregulated drugs, GPHA strongly encourages these parties to look for immediate solution in increased use of generic medicines and continue to assure the safety of our national drug supply.

Thank you to the members of the committee.

CHAIRMAN CARMONA: Thank you, sir.

I'll open the floor now for questions from the Task Force to our guests. Alex Azar?

MR. AZAR: Mr. Downey and Mr. Johnston, you both touched on this a bit, but I'd like to see if you could help us by elaborating on the issue of exclusivity and protection of innovation under the Hatch-Waxman amendment to the Food, Drug and Cosmetic Act.

As you know and as you spoke about a bit, the Hatch-Waxman amendment set up a very delicate balance between protecting innovation and also allowing the entry of generic drugs and competition into the market, and so there are exclusivities, given the patent life. There are extensions of patent. There's orphan drug exclusivity, pediatric drug exclusivity to foster certain types of innovation and research that the

Congress has found to be socially desirable.

There also are incentives to encourage the first to file to get generics onto the market here in America, the 180-day exclusivity for the first to file, the first to get approved.

If we have an importation system from other countries, how do you think that importation system would or should take account of these balances of intellectual property and protections of innovation that we have here in the United States?

MR. DOWNEY: Well, I think we have in the United States enacted laws that provide these incentives for innovation, and I don't think that we should abandon them by inference by allowing imported products to eviscerate what's been promised in terms of the incentives.

Now, you have mentioned several of them. I think one of the problems is I don't believe there is a private right of action to enforce these various exclusivities. So it would have to be, if you were to have importation, it would have to be through the structure that the government would impose. There would be no way that individual companies could assert those exclusivities.

So I think if you were to go that route, you would have to very carefully honor the congressional decision to provide the patent term restoration, the pediatric exclusivity, the 180 days of exclusivity, the data exclusivity for conducting clinical trials, the exclusivity for orphan drugs, the exclusivity for new chemical entity that doesn't have patent protection.

So all of these are important incentives to innovation, and to throw them out on the promise that the importation would somehow serve us better I think is unwise.

MR. JOHNSTON: Yeah, I think the clear message with importation would be a disincentive to challenge patents and bring generic products to market earlier, and as you mentioned there has been this delicate balance set up in the construct of Hatch-Waxman. This would certainly change the dynamics, and I think much to the disadvantage of the generic industry.

MR. AZAR: I think you and Mr. Downey had both mentioned that in Canada the generic industry is not as robust as it is here in the United States. The use of generics is not as prevalent, and the pricing is not as competitive as here in the United States.

Could you talk a bit about to what extent -- what causes that? Is it the Canadian pricing system? Is it how they negotiate the prices and set the prices for brand and generic drugs? Is it intellectual property structures that the Canadian system has?

What leads to this?

MR. DOWNEY: Well, there are several things. One, the way prices are set for generics in Canada, the first generic in the market is to be on the Ontario formulary. There is no national system. So Ontario takes the lead. It has to be priced at least seven or no more than 70 percent of the brand.

After a second generic comes to the market, that price level goes to 63 percent. They call it the 70-90 rule. It's 70 percent off, 70 percent of the original brand, and then 90 percent of the 70 percent.

And really, there are only two or three generic companies that are active in Canada, as contrasted to the United States where there are, you know, dozens of us, much more market entry, very much faster here than you do in Canada. So the dynamics of the suppliers is different. The price setting structure by the Canadian government

is different, and the consequence of both of those factors, generics end up less expensive here than in Canada.

MR. AZAR: So is it fair to say that the Canadian government suppression of brand drug prices creates less of an incentive for generics to get into the market and hence less competition?

MR. DOWNEY: Absolutely.

MR. AZAR: And hence higher prices because of less competition amongst generics?

MR. DOWNEY: Absolutely.

MR. AZAR: If I could bother Mr. Downey one more time, excuse me.

You mentioned also liability. Could you talk from a CEO perspective running a pharmaceutical company what your concerns are about liability with any importation scheme?

And I think our other experts here who spoke about counterfeit, you have issues of counterfeit drugs being brought in and obviously when a citizen takes their drug they don't always retain the packaging and retain a sample of the product for counterfeit testing after the fact, and also the labeling. We heard the story about the Russian labeling coming into the country.

You have a duty to warn under American

common law, to warn the patient and warn the doctor of the side effects, and it has to be in English and has to be FDA approved.

MR. DOWNEY: Right, right.

MR. AZAR: With importation, could you talk a little about the liability concerns and the impact they could have on the pharmaceutical industry and on citizens?

MR. DOWNEY: Well, somewhat speculative because we don't have that situation, but it would be a very significant concern to us particularly if the labeling in countries other that the United States was by law required to be different there than it is here, and so you could have product. The product itself might be fine, but it wouldn't be properly labeled for the United States, and that could very well cause liability.

I would hate to think we had to defend cases where someone's counterfeit product harmed a patient and we were held accountable for that fact, but it's not impossible for me to envision having to defend such a case. I would hope it wouldn't come to pass, it very well could.

And I don't know whether that's covered under our liability insurance, but I think I'll check when I get back to the office.

(Laughter.)

CHAIRMAN CARMONA: Other questions from Task Force? Dr. Duke.

DR. DUKE: For Mr. Howell and Mr. Theriault.

When you're describing the number of instances in which you tracked counterfeit drugs across international lines several times in those cases, could you describe the cooperation and help you got from opposite member agencies in other countries along this line?

MR. HOWELL: Most of our work in one of our newest products has been outside the United States because it was just recently approved in the United States last fall. We have had sporadic cooperation from various law enforcement and regulatory bodies around the world. Basically it has been a mixed bag.

We have had excellent cooperation with FDA and OCI. They have even looked outside the United States, but I would say that you're hit and miss overseas, and these groups purposely set themselves up in certain countries where it may take you two years to even have your case heard if you're able to bring a legal action.

So it is very difficult dealing in the

world scheme with the international.

MR. THERIAULT: And our experience has been similar to that. In fact, we had a major case about three years ago where we purchased an amount of counterfeit Viagra over the Internet, and as it turned out, although the Web site appeared to be in the U.S., the guy was actually in Thailand, and we made a number of purchases. We documented the counterfeit nature of the product.

And we went to the Thai national police over there, and got very good cooperation from them. They actually arrested about a half a dozen people, and in addition to seizing a fairly substantial amount of counterfeit Pfizer products, seized over two million counterfeit Valium tablets in a raid on one of their warehouses.

But it's very spotty. One of the things that we've done recently is sign a memorandum of understanding with the Agency for Industry and Commerce in Shanghai, and we've gotten good cooperation both at the national and provincial level in China in trying to deal with some of the source producing and distributing organizations over there.

CHAIRMAN CARMONA: Other questions? Dr. McClellan.

DR. McCLELLAN: I understand about the concerns regarding counterfeit drugs and steps that you all have outlined to deal with these counterfeit threats, but several of you also made the point that there are -- even if counterfeit can be prevented, there are differences in the drug products approved in different countries. As one of you said, there's not an international standard for either the chemical composition or the bioequivalence testing or the labeling for drugs approved in different countries.

Could you all comment a little further on the extent to which that's a prevalent issue, where the drug approved in one country may not be the same as the drug approved in another?

I know we have certainly some examples of where drugs approved in other countries are the same as FDA approved drugs, but there are a number where that's not the case, too, I take it.

MR. DOWNEY: I can give a great example. We have tried to bring a generic Premarin to market in the United States for ten years, and finally the agency has decided it has to be made from a naturally occurring source. In Canada, there is synthetic generic Premarin available and has been for 20 years.

So there is a case where our standard has precluded a generic entry where it's permitted in Canada.

There are other differences in Canada. There's a difference in how you supplement your application to change raw material suppliers. There are differences in standards which you can implement unilaterally as opposed to what can be implemented with preapproval in Canada versus the United States. There are quite significant differences.

CHAIRMAN CARMONA: Other questions from the Task Force? Yes, Dr. Crawford.

DR. CRAWFORD: I was going to ask Ms. Williamson.

You had talked about, pursuant to Dr. McClellan's question, you had talked about ICH developing standards. If you could speculate, how would those be adopted by member countries? Would that require some sort of formal process or would simply the ICH standards be advisory?

MS. WILLIAMSON: Well, I think it's important to note that when we talk about ICH, we're talking about a series of guidances. So they don't replace the regulations that are set in the United States or in any other region.

So essentially they are guidances that are specific to very certain aspects of drug registration and what is required to review those registrations.

However, the discretion still lies within the specific region, whether it's the FDA or the European health community or Japan for making the ultimate judgment based on the totality of the information as to whether or not the standard has been met for safety and efficacy in their area.

So it's important to note that I think in terms of insuring the least amount of redundancy in some level of common standards, whether it's in developing a particular assay or whatnot, but it is helpful to have these guidances, but they don't replace the regulations that are rigorous here or the judgment of the members of the reviewers of the Food and Drug Administration.

CHAIRMAN CARMONA: Questions? Oh, let me see. We'll get Dr. O'Grady now and then we'll get Dr. Duke.

DR. O'GRADY: I had a couple of questions.

Mr. Dempsey, you said in your testimony that you're getting at least close, if you're not already there, with about 80 percent of your sales

will have some form of anti-counterfeiting measures going on. I guess two questions related to that.

What did that end up costing you? And what percentage of the problem do you think you covered by taking those steps?

MR. DEMPSEY: In terms of cost, we don't put that number out. We don't quantify that number. When we first looked at the issue in the marketplace it was decided that we would move whatever the costs were going to be. So our implementation of our short-term brand security program, which included both overt and covert features moved forward and cost.

To date we have never sat down and quantified the entire cost of putting the security measures in place, although I will say they are sizable.

In terms of the short-term anti-counterfeiting technology, and I believe your question was how much of that would it --

DR. O'GRADY: Yeah. I mean, given how much you've invested at this point to get to 80 percent of your products or of your sales, what percentage of the problem do you think you've covered? How much do you think you've been successful at offsetting 50 percent of the

counterfeiting, 25, 75 percent? Do you have a feel for effectiveness of the measures?

MR. DEMPSEY: I think it's important to note that when you look at anti-counterfeiting technology, you have both a short-term plan and a long-term plan, and our short term was what was currently available in the marketplace, whether it be color shifting ink that's used by the Treasury Department, tag-ins in the Security Inc.'s, watermarks, holograms, carton closure seals. Those are all short-term things that you have to change on a periodic basis in order to keep your plan effective, the long term being radio frequency identification tags, which I have to really emphasize that that's further off than was presented by the earlier panel from our perspective.

So in terms of did it cover the problem and how much did it eliminate, it's hard for me to answer that because my fear is that tomorrow I'll get the phone call from the Office of Criminal Investigation, from Dave Bourn down in Miami, and he says, "John, we've got a problem. We found some product that we think is questionable."

So I'd like to think that we've made our product very secure, but I'm also well aware

that I could get a phone call tomorrow that would indicate that there has been an issue that has been uncovered that we have to investigate.

The folks that are out there doing this counterfeiting are very sophisticated. They're oftentimes tied to organized crime, and where there's money to be made, they'll invest as much as they can as long as there's a return on their investment.

And certainly the penalties in the United States to date are minimal compared to penalties involved with the sale or production of illegal drugs.

So I'm very concerned on a daily basis that I'll get that phone call.

DR. O'GRADY: Mr. Theriault?

MR. THERIAULT: Yeah. If I might comment on that one, when you reviewed the Lipitor case I cited, 18 million tablets recalled, regardless of how much anti-tampering or anti-counterfeiting technology Pfizer might have put into its packaging and products, it would have been entirely defeated because repackagers were allowed to discard the original packaging and repackage the product.

So whatever your investment is, as long

as repackaging is allowed can be defeated.

DR. O'GRADY: Got you. All of you make a fairly compelling case about the problem of counterfeiting and how serious it can actually be. At the same time I'm not so sure that consumers are particularly aware of this. Can any of you or all of you give me a feel for what your companies are doing to make the general public aware of the sort of horror stories that you've told us today?

MR. DEMPSEY: From our standpoint, when counterfeit product label with Procrit was first identified, we worked in conjunction with FDA and up on our Web site immediately put out the distinguishing features between authentic product versus counterfeit product, and above and beyond that, linked to the FDA's Web site so that the consumers who weren't aware of our Web site could at least go to the FDA's Web site.

In addition, we put together a, for lack of a better word, a brochure, a Slim Jim that our sales force carried out to physicians, nurses, case managers, retail pharmacists that talked about the issue of counterfeit drug in the marketplace, what we as Ortho-Biotech did in order to prevent it, and we found that to be very effective.

But in terms of how much the general

public is aware of it, I think as long as you receive the solicitations to purchase drugs over the Internet, the general public is going to purchase those products.

We recently had an issue where a woman purchased Ortho Evra, which is a contraceptive patch, over the Internet, and when she got it, she fortunately saw that it didn't look like the authentic patch that she had been using, and she notified authorities.

And as it turns out, that product was sourced from India and was purchased over an Internet site that was labeled as a Canadian Internet site. So no matter what you do, you can do as much as you can with education, but as long as these Internet solicitations continue to come in, people are going to purchase.

MS. WILLIAMSON: If I could just add a couple of comments onto that, I think it's an important, very important observation because unless you personally have been involved in instances where you've had to manage or deal with counterfeiting, the consumer -- and we're all consumers; let's face it -- go into our neighborhood pharmacies believing that what we get prescribed by our physicians is what we will be

receiving.

In terms of consumer awareness, we certainly have gone through the things that I outlined earlier in terms of posting things to Web sites, outreach to the community, press releases, direct letters to pharmacists, wholesalers, and whatnot.

But we also take the opportunity, such as instances that we've got here today where, whether it's testifying on the part of a prosecution that's being developed or providing comments that are publicly available, we also do that.

DR. O'GRADY: I guess I would only as follow-up say that certainly you represent an industry that is leading in terms of communication to the public, and this seems a fairly important topic to add to your communication plans.

Could I ask a question of Mr. Johnston, please, having to do with a number of things you brought up?

I mean, this whole discussion of importation probably wouldn't even be going on if prices between different countries were a little more similar. Do you see that in terms of when we think about generics and some of the discussion

that went on about price differentials that if there was an importation scheme that was sort of fully implemented at this point that there would -- given how much generic substitution goes on in current American health plans and whatnot, would you expect there to be much of an effect of importation in terms of the use of generics in the United States?

MR. JOHNSTON: Let me clarify that. You're suggesting that if generics from outside the country were permitted to be imported, what impact that would have?

DR. O'GRADY: Or even -- and I don't want to put words in the mouth of the discussion that went on before, but the thread of what I got where you have a price control over a brand name, that there's less sensitivity, I mean, that there's not much in it for the consumer to shop for generics and whatnot if the price has been suppressed on the brand name drug.

And there are some examples, I think, from Mr. Downey's where he looks at German prices and they are fairly close.

So I guess what I'm wondering about is when we think about the things that can go on to reduce the average American's spending on

prescription drugs, one of the things that certainly American health plans currently turn to is generics and the use of generic substitution in their benefit design and other issues like that.

So I guess one of my questions was if we thought you went to something that was an importation scheme, given health plans' current heavy encouragement of generics, what would we see in terms of -- I mean, how much savings would we actually see or would things -- we're already talking about domestic generics that are cheaper than imported generics, and sort of where are -- are there savings involved in importation if we're already talking about -- I forget. Someone else used the percentage of what percentage of drug spend is in generics at this point.

MR. DOWNEY: Eight percent.

DR. O'GRADY: Eight percent?

MR. DOWNEY: No, more than that

PARTICIPANT: Fifty percent of the scripts.

DR. O'GRADY: More than half of prescriptions.

MR. DOWNEY: Right.

DR. O'GRADY: But it's less --

MR. DOWNEY: Than ten percent of

dollars.

DR. O'GRADY: Of dollars.

MR. DOWNEY: So there's very substantial savings, as you can see.

MR. JOHNSTON: Yeah, I think the competition in the U.S. marketplace among generics will certainly drive the cost of any eligible generic product down substantially. FDA typically approves for a blockbuster brand drug eight, ten, 12 products when the patent expires. So there is very significant price erosion.

The one thing that we didn't touch on though that I would like to just bring out is that the U.S. has a very strict scheme for approving generic drugs. They have to follow a very rigid approval process and demonstrate bioequivalence to the U.S. marketed brand product.

Now, I think that's very important when we think about a more wide-open scheme. If you bring in a generic from England, from Germany, from India, those aren't tested against the U.S. marketed product. So if you bring in the brand, I think, patients and health care practitioners might assume that they are bioequivalent and can be readily interchanged brand from England for the U.S. brand, brand from India.

Well, in fact, they may have different characteristics, and when you think about it in terms of anticoagulant or other narrow therapeutic drug, you certainly will have wide variation and potentially cause the patient harm because of this type of interchangeability that is not controlled as we have now in the U.S.

MR. DOWNEY: In some places it's not even proven. The same standards don't apply.

DR. O'GRADY: Okay. You bring up a point in your testimony about $21 billion in biotech right now.

MR. DOWNEY: Yes.

DR. O'GRADY: And I guess I was wondering can you be any more specific of if there was a generic parallel there of what you think those savings would be?

MR. JOHNSTON: Well, I think right now it's speculation because we don't have that abbreviated process, but clearly if the Hatch-Waxman paradigm is any indicator, we would have to believe there would be significant savings in the biopharmaceuticals as well.

MS. WILLIAMSON: May I add a comment to that?

DR. O'GRADY: Sure.

MS. WILLIAMSON: I would just like to add that with respect to the biotech products, what was mentioned earlier in terms of testing and the difficulties in testing, that's compounded when you're talking about biologics and proteins that are manufactured using recombinant DNA technology. So it becomes even more of a challenge to demonstrate comparability or bioequivalence.

CHAIRMAN CARMONA: Mr. Azar?

MR. AZAR: I just had one additional question for Mr. Downey. One thing that I was struck by at the last hearing that we had where the consumer groups testified before us was that everybody seemed to be in agreement that any drugs that come into this country under a legal importation scheme should meet the FDA's gold standard, the comprehensive regulatory regime that you referred to in your remarks, and that includes manufacturing, good manufacturing practices at the manufacturer's site, which includes the distribution, control over the distribution mechanism, and the labeling and the product composition.

To what extent, if a regime is set up by Congress for the legal importation of drugs, to what extent does the success of that depend on the

voluntary cooperation of manufacturers in their foreign manufacturing facilities, the cooperation of foreign distributors, foreign pharmacies in complying with this domestic regulatory regime in order to insure that whatever would be imported would meet the FDA gold standard?

MR. DOWNEY: Well, I think the way to do that is what we're doing now, directly require foreign companies that want to compete in the United States to undergo an NDA/ANDA process. Absent that review and the control over that entity, I don't see how the agency can regulate it.

MR. AZAR: But I think that we have seen from some of the drug companies that have actually restricted the sale of drugs into Canada and from the remarks of many of you today, that the importation into the United States of Canadian price controlled drugs -- I'm just using Canada as one example -- is not something that you necessarily would want to be -- that you're saying you're in favor of and would want to support.

So to what extent would it require that companies like yours, United States companies, that you essentially be co-opted and cooperate in a system to import price controlled drugs into the United States?

MR. DOWNEY: Well, we do very little business in Canada, and I don't think we would expand it if I thought that price controls would be exported back to the United States.

I don't know if that answers your question, but I think it's legitimate for companies in the United States to say, "We aren't going to play in that game."

I actually think that what we should be doing as a country is urging other countries to eliminate their price controls so they pay their fair share of the R&D budget in the United States. It should be going the other way.

MR. AZAR: Do the representatives of any of the other companies that have maybe a large international presence, if you'd like to chime in there in terms of if you're at Pfizer, for instance and you've got a foreign manufacturing facility? Presumably you'd need to consent to let our FDA inspectors go in currently for drugs that you might manufacture abroad and send to the United States under an NDA.

You agree to have us come into your facility for inspection. You manufacture according to good manufacturing practices. You get it back into the country through very tightly controlled

distribution systems. Presumably it would require that you all agree to an expansion of our regulatory reach within your manufacturing facilities and that you'd have to cooperate, right?

MR. DEMPSEY: Yes, I believe that's correct.

MR. AZAR: Is that something you all would do?

MR. DEMPSEY: It's being my area of responsibility.

MR. SACHDEV: Coming back to the theme of counterfeit because it's clearly something that's prevalent in all of your testimony, Mr. Theriault, you mentioned in your testimony that you had many examples of counterfeits of the Pfizer products including Viagra and Lipitor from countries all over the world, including I think you said Thailand and China with schemes where the active ingredients are being produce in one country, the labeling is being produced in another country.

That seems to indicate that there's a pretty sophisticated operation going on.

We have heard from some others that this is primarily a problem overseas and not necessarily a problem. I think in your written

statement you talk about counterfeiting in Canada in particularly with regard to Viagra in a case that you uncovered last year.

Can you elaborate on that case, in particular?

MR. DEMPSEY: We did develop one case in Canada. In fact, the RCMP and the Drug Enforcement Administration together located a Viagra manufacturing facility in Quebec.

But that was a fairly small operation. What I think we'd like to convey with the testimony is that this is not really a scheme anymore. This is not a small activity that's being engaged in pockets here and there. This has become a very, very big business involving organized crime, involving international distribution networks, and yes, the Lipitor case is a good example.

You know, you had API that was imported into Costa Rica from Switzerland, probably originated in India. You had punches and dies that came from the United States, and you had the product manufactured in the Caribbean and distributed throughout the United States, 18 million tablets.

We see similar operations in Asia where

the product is produced in China. The packaging is out of Korea in some cases. The distribution comes out of Hong Kong and Taiwan. You're not dealing with small, little pockets of criminal activity. You're dealing with real serious organized crime.

MR. SACHDEV: Putting aside whether or not we recommend or Congress decides to legalize importation, when you have a situation or you have bought Lipitor that has commingled product, some of it with active ingredient, some of it completely counterfeit, and some of it actual product, what kind of steps are your companies taking to try to combat that type of counterfeiting?

MR. DEMPSEY: Well, we're doing all of the anti-counterfeiting things in packaging and in the product that, you know, my Johnson & Johnson colleague mentioned. We're at a disadvantage if you will when you can take our packaging, discard it, take our product, commingle it with counterfeits, put it in your own package, and then distribute it.

And there was a question to the previous panel about testing and the cost of testing and that sort of thing. You think about this. Six hundred thousand, 30 count Lipitor bottles distributed in the United States. If you

wanted to be 100 percent sure that there was no counterfeit in there, you would have to test every one of those 18 million tablets.

You know, it's a complex problem, and I think the companies are doing everything they possibly can to combat it, but I think the current system is being played by people who are making a lot of money on counterfeit and diverted product right now.

MR. SACHDEV: Just one more follow-up question on that. Several of you, including Ms. Williamson, mentioned the Internet and I think you mentioned the eBay site. Can any of you characterize the extent to which you think counterfeiting is being facilitated by the Internet operations versus maybe other, more traditional outlets?

MR. HOWELL: Well, in our experience the distribution via the Internet negates any anti-counterfeiting technology a company would choose to apply. It's a direct distribution into the country, and it's unregulated.

A very great concern. So we all are participating in the various anti-counterfeiting technologies and looking for the future, both short-term and long-term as we have heard here

today, but there are elements of this distribution by design to reach consumers without going through anyone with a scanner, a wand, or any way to authenticate the product.

MS. WILLIAMSON: I would just like to add since you mentioned that example that consumers more and more these days are using the Internet for an abundance of things, and I think it's very important to really put out the buyer beware message because as some of the people at the panel here mentioned, what may appear to be a Web site that's in the United States or American product, you can find could be something that's actually located 5,000 miles away in circumstances for which can't be controlled, and at the point where the consumer realizes that might be before they take the product or it might be after they take the product, and at that point it's a little too late.

CHAIRMAN CARMONA: thank you.

CHAIRMAN CARMONA: I have just a quick question more globally. You know, the premise is that we have the most sophisticated, robust system in the world to insure integrity of our products and authentication of those products, and yet it seems that very learned individuals, both with the

science technology, those in law enforcement backgrounds and such, are challenged every day to stay abreast with our adversaries who continue to provide countermeasures against everything we do because of the level of sophistication that they have.

So in chasing the Holy Grail of importation and whether we could every do it safely, the question I would pose to you is: is it reasonable to think that we could get to the point where we would have a cost effective system developed that would insure the protection of all products that would be imported and ultimately go to the American public?

MS. WILLIAMSON: Based on the information that we have available today, I think it would be difficult to imagine that without the varied issues that have come up, all being addressed. And in doing so, certainly it would be extremely challenging to insure that you could do that 100 percent.

MR. DEMPSEY: I would just add to that that we have a controlled, regulated system now in the United States, and look at where we're at.

CHAIRMAN CARMONA: Exactly.

MR. DEMPSEY: I don't know how we could

do it. RFID is appealing, but it took us 18 months to put a chip and antenna on a vial. In order for RFID to be effective you'd have to put it on each individual unit of use. We're a ways away.

CHAIRMAN CARMONA: Well, I appreciate your candor. Any other comments to that?

I mean, it's certainly a concern of mine that we are pushing the limits of technology, and even with technology considering the potential use cost of trying to implement such a system and then with all of that being done, can we step back and have the Secretary in our case at HHS be able to insure the American public that all products are now safe?

Okay. Other questions from our Task Force members?

(No response.)

CHAIRMAN CARMONA: If not, that will conclude our deliberations today. Thank you so much for coming to us and educating us and spending the time with us. We really appreciate that.

Thank you.

We'll stand adjourned.

(Whereupon, at 4:30 p.m., the meeting in the above-entitled matter was concluded.)